EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

10 June 2015

(Testing proposal – Third party consultation procedure – Administrative efficiency – Information in other registration dossiers – Article 25(1) – Duties of the Agency)

Case number	A-001-2014
Language of the case	English
Appellant	CINIC Chemicals Europe Sárl, France
Representative	Ruxandra Cana and Indiana de Seze Steptoe & Johnson LLP, Belgium
Intervener	PETA International Science Consortium, Ltd (PISC), United Kingdom
Contested Decision	TPE-D-0000003219-74-05/F of 15 October 2013 adopted by the European Chemicals Agency pursuant to Article 40 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; hereinafter the 'REACH Regulation')

THE BOARD OF APPEAL

composed of Mercedes ORTUÑO (Chairman), Andrew FASEY (Technically Qualified Member and Rapporteur) and Barry DOHERTY (Legally Qualified Member)

Registrar: Sari HAUKKA

gives the following

Decision

Summary of the facts

1. On 15 January 2014, the Appellant lodged the present appeal requesting the Board of Appeal to, in particular:
   - annul the Contested Decision in so far as it requests the Appellant to carry out an OECD 443 extended one-generation reproductive toxicity study (hereinafter 'EOGRTS');
   - order the European Chemicals Agency (hereinafter the 'Agency') to initiate a new testing evaluation procedure or, in the alternative, to re-open the testing evaluation procedure, for the same endpoint; and
   - order the refund of the appeal fee paid by the Appellant.
2. In the event that the appeal should be found to be inadmissible or be dismissed, the Appellant requests the Board of Appeal to rule that the deadline set in the Contested Decision should be interpreted, in light of Article 91(2) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise), as referring to 24 months from the date of the final decision of the Board of Appeal.

Background to the dispute

3. On 21 February 2011, the Appellant submitted an inquiry to the Agency pursuant to Article 26 for the substance 3,6-bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (hereinafter the 'Substance'). According to the Parties, the Substance is a non-phase-in substance previously notified in accordance with Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).
4. On 24 May 2011, the Agency informed the Appellant by letter that a substance with the same EC number had previously been registered by other companies. The Agency provided the Appellant with the contact details of those previous registrants and an indication of the existing information available with respect to the Substance. In particular, for the purposes of the present case, the Agency informed the Appellant that no information was available for screening for reproductive/developmental toxicity as required under Section 8.7.1 of Annex VIII. The Agency also reminded the Appellant of its joint submission and data sharing obligations under the REACH Regulation.
5. On 15 August 2011, according to the Appellant, the Appellant commissioned an OECD 421 screening study in order to fulfil the information requirement under Section 8.7.1 of Annex VIII.
6. On 1 February 2012, another registrant (hereinafter the 'other registrant') submitted an inquiry for the Substance pursuant to Article 26. On 14 March 2012, the other registrant submitted a registration dossier to the Agency at the 1 to 10 tonnes per annum tonnage band before receiving the Agency's reply to the inquiry. On 28 March 2012, the Agency provided the other registrant with the same information it had provided to the Appellant in response to its earlier inquiry. The Agency also informed the other registrant of the identity of the Appellant as a potential registrant.

7. On 28 March 2012, the Agency informed the Appellant of the other registrant's inquiry and its contact details. The Agency also reminded the Appellant of its joint submission and data sharing obligations under the REACH Regulation.

8. On 27 April 2012, information contained in the other registrant's registration dossier was disseminated on the Agency's website. This did not include any information on an OECD 421 screening study.

9. On 6 July 2012, the Appellant registered the Substance at the 10 to 100 tonnes per annum tonnage band. The Appellant's dossier included a robust study summary of the OECD 421 screening study it had conducted in order to satisfy the requirement set out in Section 8.7.1 of Annex VIII. In view of the fact that the study showed a degree of pup mortality, the Appellant included in its registration dossier a testing proposal for an EOGRTS to address that concern.

10. Following the Appellant's testing proposal, between 25 September and 12 November 2012, the Agency held a third party consultation pursuant to Article 40(2) on 'reproductive toxicity (two-generation reproductive toxicity)'. The Agency received third party information in response to this consultation but, according to the Contested Decision, the Agency considered that the information received was not sufficient to fulfil the information requirement.

11. On 27 September 2012, the Appellant contacted the other registrant and informed it that it owned '*data (OECD 412* [sic] *and 425) according to Article 26 and 27*'. Subsequently, on 8 February 2013, the Appellant corrected its statement to the effect that some of the data was for an OECD 421, rather than an OECD 412, study.

12. On 18 December 2012, information contained in the Appellant's registration dossier was disseminated on the Agency's website. This included information that the report date for the Appellant's OECD 421 screening study was 25 June 2012.

13. On 7 January 2013, the Agency sent to the Appellant the draft decision requiring the Appellant to conduct the proposed EOGRTS and invited it to provide comments. The Appellant did not provide comments within the 30-day commenting period.

14. On 8 March 2013, the Agency notified its draft decision on the Appellant's testing proposal to the Member State Competent Authorities (hereinafter 'MSCAs'). Proposals for amendment were received from two MSCAs and, on 11 April 2013, the Appellant was invited to provide comments on those proposals for amendment. The Appellant did not provide comments on the proposals for amendment. The Contested Decision was not amended following the MSCAs' proposals for amendment and the draft decision was referred to the Member State Committee (hereinafter the 'MSC') on 22 April 2013.

15. On 13 June 2013, the MSC unanimously agreed on the draft decision on the Appellant's testing proposal.

16. On 24 June 2013, the other registrant updated its registration dossier from 1 to 10 tonnes per annum to 10 to 100 tonnes per annum. In its update the other registrant included an OECD 421 screening study, the study report of which was dated 6 November 2012. This screening study was performed using a different sub-strain of rats and a different vehicle to those used in the Appellant's OECD 421 screening study. Information contained in the other registrant's updated registration dossier was disseminated on the Agency's website on 15 August 2013. According to this information, the OECD 421 screening study performed by the other registrant showed that the Substance '*…revealed no parental, reproductive or developmental toxicity…*'.

17. On 15 October 2013, the Agency adopted the Contested Decision on the Appellant's testing proposal which stated inter alia the following:

'This decision does not take into account any updates after 8 March 2013, the date upon which [the Agency] notified its draft decision to the [MSCAs] pursuant to Article 51(1)….

[…]

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) … using the indicated test method and the [Substance]…:

- *[EOGRTS] in rats, oral route (test method: OECD 443).*

Pursuant to Article 40(4) and 22…, the Registrant shall submit to [the Agency] by 15 October 2015 an update of the registration dossier containing the information required by this decision.

At any time, the registrant shall take into account that there may be an obligation to make every effort to agree on sharing information and costs with other Registrants.'

18. Between 14 October and 8 November 2013, the Appellant exchanged communications with the other registrant in which it informed the latter inter alia that it was interested in assessing the relevance of the other registrant's OECD 421 screening study to the Appellant's registration and the need to perform an EOGRTS.

19. On 8 November 2013, the Appellant sent a letter to the Agency asking inter alia whether it had taken into account during the decision-making process the other registrant's OECD 421 screening study which showed no concerns regarding reproductive toxicity. On 22 November 2013, the Agency replied that '*information not included in the dossier with [the Appellant's] submission number has not been considered in the decision making process*'.

20. On 14 March 2014, the Agency sent separate communications to the Appellant and the other registrant. However, this letter was received by the Appellant for the first time during the present proceedings as part of the Defence served on the Appellant on 14 April 2014. In the letter, which was later resent to the Appellant by mail and REACH-IT, the Agency recognised that the OECD 421 screening study performed by the other registrant may be relevant for the Appellant's considerations on whether or not to perform the EOGRTS. The Agency also reminded the Appellant and the other registrant of the joint submission and data sharing provisions of the REACH Regulation. The Agency also encouraged the two registrants to exchange and analyse the data possessed by each and decide whether there was still a need to perform the test required in the Contested Decision.

Procedure before the Board of Appeal

21. On 15 January 2014, the Appellant lodged the present appeal at the Registry of the Board of Appeal.

22. On 5 March 2014, since a member of the Board of Appeal was precluded from participating in the proceedings, the Chairman, pursuant to 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; hereinafter the 'Rules of Procedure'), designated an alternate member, Barry Doherty, to act in the present case as the legally qualified member of the Board of Appeal.

23. On 17 March 2014, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.

24. On 8 and 9 April 2014 respectively, the PETA International Science Consortium, Ltd (hereinafter 'PISC' or the 'Intervener') and the European Coalition to End Animal Experiments (hereinafter 'ECEAE') applied separately to intervene in the proceedings before the Board of Appeal supporting the remedy sought by the Appellant.

25. By separate decisions of 2 June 2014, the Board of Appeal, having heard the Parties, granted both applications to intervene. On 8 August 2014, ECEAE informed the Board of Appeal that it no longer wished to act as an intervener in the present case.

26. On 14 April 2014, the Board of Appeal requested the Agency and the Appellant to respond to certain questions. The Parties duly lodged their replies on 20 May 2014. On the same date the Appellant also lodged its observations on the Defence.

27. On 18 August 2014, the Appellant lodged its observations on the Agency's reply to the questions posed by the Board of Appeal.

28. On 9 September 2014, the Intervener submitted its further observations.

29. On 11 September 2014, the Agency lodged its observations on the Appellant's observations on the Defence and on the Appellant's reply to the questions posed by the Board of Appeal.

30. On 13 October 2014, the Agency submitted its observations on the Intervener's observations. On the same date, the Appellant informed the Board of Appeal that it had no observations on the Intervener's observations.

31. On 30 October 2014, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 11 November 2014, the Agency informed the Board of Appeal that it did not request a hearing to be held. On 13 November 2014, the Appellant requested a hearing to be held. As a result, in accordance with Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 12 February 2015. At the hearing, the Parties and the Intervener made oral presentations and also responded to questions from the Board of Appeal.

Reasons

32. In support of the form of order sought the Appellant claims firstly that the Contested Decision was adopted in breach of the Agency's obligation to take into account all information available to it, including information submitted to it as part of another registration dossier for the Substance. The Appellant claims that the Agency's failure to assess the information in other registration dossiers also breached several provisions of the REACH Regulation, the Appellant's legitimate expectations, and the principle of proportionality.

33. The Appellant claims secondly that, by failing to take into consideration information available in other registration dossiers, the Agency breached Article 25 which requires that testing on vertebrate animals for the purposes of the REACH Regulation shall be undertaken only as a last resort.

34. The Appellant claims thirdly that the Contested Decision was adopted in breach of an essential procedural requirement, as well as Article 40(2), which requires that certain information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency's website.

35. The Appellant claims fourthly that the present appeal is the only opportunity available to it to continue its business activities in full legal certainty.

36. The Board of Appeal will firstly examine the Appellant's claim that the Contested Decision was adopted in breach of an essential procedural requirement and Article 40(2).

Alleged breach of an essential procedural requirement and of Article 40(2)

37. The Appellant states that, taking into account Column 2 of Section 8.7.1 of Annex VIII, it had proposed to conduct an EOGRTS whereas the subject of the Agency's third party consultation was a 'reproductive toxicity (two-generation reproductive toxicity)' study.

38. The Appellant argues that by opening the third party consultation on an endpoint, 'reproductive toxicity (two-generation reproductive toxicity)', rather than the actual test proposed, EOGRTS, the Agency breached an essential procedural requirement and acted contrary to Article 40(2). The Appellant claims that such an error should lead to the invalidity of the Contested Decision. In particular, the Appellant considers that the Agency's actions did not provide third parties with precise information as to the testing proposal submitted by the Appellant. According to the Appellant, knowledge of the exact test proposed could have allowed third parties to comment on this aspect and those comments could have been relevant to the decision on the testing proposal. The Appellant claims that the Agency's third party consultation did not allow the other registrant to be aware that the Appellant was proposing to conduct an EOGRTS on the basis of the results of the OECD 421 screening study performed by the Appellant.

39. The Agency submits that Article 40(2), read together with Recital 64, does not require the Agency to publish the specific test proposed by a registrant to meet a specific endpoint. The Agency states that it is apparent from the information submitted by the Appellant and the legal basis referred to, namely Column 2 of Section 8.7.1 of Annex VIII, that vertebrate testing was proposed to address the hazard endpoint for reproductive toxicity (two-generation reproductive toxicity), as prescribed by Section 8.7.3 of Annexes IX and X. The Agency claims that the endpoint the testing proposal was intended to address was therefore presented correctly in the third party consultation.

40. In addition, the Agency argues that the information available in the public consultation contained sufficient information to permit third parties to submit relevant comments, which they did in this case. Furthermore, according to the Agency, the third party consultation is not intended to gather information from registrants of the same substance. The Agency states that there are other specific processes to facilitate interaction between existing and potential registrants of a substance, such as the inquiry process, data sharing and joint submissions.

41. The Agency claims that the purpose of the third party consultation is to inform stakeholders that a testing proposal has been made to meet a specific endpoint. This allows any interested parties who have, according to Recital 64, '*scientifically valid information and studies that address the relevant substance and hazard endpoint…*' to inform the Agency about such information. As a result, the role of third parties is strictly to inform the Agency whether they have valid scientific data that addresses the relevant substance and hazard endpoint. According to the Agency, the announcement in the public consultation rightly only refers to the name of the substance and the hazard endpoint investigated as this gives sufficient information to allow third parties to provide information that may be relevant to the Agency's assessment of whether the test proposed is required.

42. The Intervener argues that, although Article 40(2) states that the Agency shall publish the hazard endpoint for the vertebrate testing proposed, greater clarity could be provided to third parties if the actual test, rather than the relevant endpoint, were published.

Findings of the Board of Appeal

43. As a preliminary observation, the Board of Appeal notes that in the present case the Appellant proposed an EOGRTS as a means to investigate the concerns identified in the OECD 421 screening study it had previously performed in accordance with Section 8.7.1 of Annex VIII. The Board of Appeal considers that it is clear from the information provided by the Appellant in its registration dossier that this testing proposal addresses Section 8.7.3 of Annex IX, namely the two-generation reproductive toxicity study requirement. In this respect, the Board of Appeal observes that, according to the Agency's News Alert of 15 February 2012 (ECHA/NA/12/02), an EOGRTS can '*…under certain conditions, fulfil the current information requirements for a two-generation reproductive toxicity study*'. The News Alert clarifies that registrants now have a choice between a two-generation reproductive toxicity study (OECD 416) or an EOGRTS (OECD 443) to satisfy the two-generation reproductive toxicity information requirement. The Board of Appeal further notes that the response by PISC to the third party consultation conducted by the Agency includes a request for the Agency to direct the registrant to perform an EOGRTS using only one generation. The Board of Appeal find therefore that interested parties were not prevented from providing information on the actual test proposed.

44. The Board of Appeal observes that, pursuant to the first sentence of Article 40(2), '*[i]nformation relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website.'* The second sentence of that provision sets out the precise information that should be published, namely *'…the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required.'* Recital 64 of the REACH Regulation states that *'…interested parties should have a period of 45 days during which they may provide scientifically valid information and studies that address the relevant substance and hazard end-point, which is addressed by the testing proposal…'.*

45. To comply with Article 40(2), the Agency is therefore required to publish the substance name, the hazard endpoint for which vertebrate testing is proposed and the deadline for responding to the consultation. The Agency is therefore not required by the REACH Regulation to publish details of the actual test proposed by a registrant to meet a specific endpoint.

46. In the present case, the Agency published on its website the name and EC number of the Substance, the date of publication of the consultation and the deadline for submitting relevant information. In addition, under the heading entitled 'hazard endpoint for which vertebrate testing was proposed', the Agency inserted 'Reproductive toxicity (two generation reproductive toxicity)', which is the endpoint that the testing proposal was intended to address.

47. In view of the above, the Board of Appeal finds that in the present case the Agency conducted the third party consultation in accordance with the requirements of Article 40(2). The Appellant's plea must therefore be dismissed as unfounded.

48. The Board of Appeal considers however that, whilst it is not legally obliged to do so, the Agency should consider, in certain cases, making third party consultations more explanatory so that all possibly relevant data is made available to the Agency to help it in deciding whether to approve, modify or reject testing proposals. In certain circumstances this could entail publishing in the third party consultation the actual test proposed, as well as the hazard endpoint in question. This could also contribute to fulfilling the Agency's obligations under Article 25(1) to ensure that testing on vertebrate animals is only undertaken as a last resort.

Breach of the Agency's obligation to take all information available to it into account, including information submitted to it as part of another dossier on the Substance

49. The Appellant argues that in exercising its discretion the Agency must assess all elements of fact which may have an impact on the decision to be taken. The Appellant claims that in adopting the Contested Decision the Agency made an error of assessment since it did not take into account all the relevant factors and circumstances of the situation that the act was intended to regulate. In this respect, the Appellant argues that the Agency is under an obligation to take into account not only the information submitted by the Appellant in its dossier and information received from the third party consultation conducted pursuant to Article 40(2), but also any information contained in other dossiers for the Substance. The Appellant claims that, in adopting the Contested Decision, the Agency breached that obligation by not taking into account the OECD 421 screening study contained in the dossier submitted for the Substance by the other registrant.

50. The Appellant further states that, under the REACH Regulation, registrants must take into account all relevant and available information for the purpose of assessing the risks posed by their substances and compiling their registration dossiers. The Appellant claims that the same obligation applies to the Agency's examination of testing proposals under Article 40, since to do otherwise would impose a different standard of review on the Agency than on registrants. The Appellant argues that, whereas the Agency would have been obliged to take the information at issue in the present proceedings into account if it had been submitted during the course of a third party consultation, if it were not obliged to consider the information contained in other dossiers, some information would have a different status depending on the context in which it is submitted.

51. The Appellant claims further that the duty of sound administration incumbent upon the Agency obliges the latter to adopt its decisions on the basis of all information which might have a bearing on the result, including in the present case the other registrant's OECD 421 screening study. The Appellant claims that, by failing to assess all the relevant information available to it, the Agency failed to ensure that testing on vertebrate animals was undertaken only as a last resort, as required by Article 25.

52. The Appellant claims that as long as the update of the other registrant's dossier was made before the final decision was adopted by the Agency the information contained therein should have been taken into consideration. The Appellant adds that the Agency's cut-off point for new information to be considered in the decision-making process, specifically the date the draft decision is sent to the MSCAs for proposals for amendment (hereinafter the 'cut-off point'), is a measure of administrative convenience and not a legal requirement. The Appellant claims furthermore that such self-imposed limitations cannot be used against registrants when the clearly disproportionate outcome of such a course of action is likely to be unnecessary animal testing. The Appellant also claims that the last resort principle contained in Article 25 should overcome measures of simple administrative convenience.

53. The Appellant argues that if the Board of Appeal considers that the obligation to take into account information contained in other dossiers submitted for the same Substance is not literally spelled out in the REACH Regulation, such an obligation can be inferred from the intentions and regulatory framework of that Regulation consistent with a teleological interpretation.

54. The Appellant also claims that the data sharing provisions in Articles 26 to 30 are not directly applicable to the present case, since those provisions apply to potential registrants or members of a Substance Information Exchange Forum (SIEF) of which the Appellant and the other registrant are neither. The Appellant also claims that the joint submission provisions set out in Article 11 are not applicable to the present case.

55. The Appellant highlights that, according to Section 2.1.6.1 of the Agency's Guidance on Dossier and Substance Evaluation (June 2007), '*[i]n order to accomplish its tasks, the Agency should also check the information in other registration dossiers available for the same substance*'. The Appellant claims that this statement created legitimate expectations that the Agency would assess the information submitted for the relevant endpoint in other registration dossiers for the Substance before adopting the Contested Decision, irrespective of the time at which the relevant information was submitted.

56. In addition, the Appellant, supported by the Intervener, argues that the Agency's refusal to take into account the other registrant's OECD 421 screening study before the adoption of the Contested Decision, in conjunction with its refusal to assess the Appellant's dossier update before the deadline set in the Contested Decision, has placed the Appellant in a situation of intolerable legal uncertainty. According to the Appellant and the Intervener, the Agency has created, in effect, an incentive to perform a potentially unnecessary study on vertebrate animals to ensure compliance and legal certainty.

57. The Appellant claims that the Contested Decision, and specifically the requirement to perform an EOGRTS, breached the principle of proportionality as, by not taking into account the separate screening study submitted by the other registrant, the Agency failed to demonstrate that the testing required did not exceed the limits of what is necessary to attain the objectives legitimately pursued by the measure in question.

58. The Agency claims that the Appellant's own failings contributed to the situation in which it finds itself as it has breached the obligation to share information with other registrants and to submit a joint registration, pursuant to Articles 26 and 11 respectively. The Agency claims that these obligations apply to both phase-in and non-phase-in substances. The Agency also claims that it reminded the Appellant and the other registrant of these obligations, in particular in its letters of 28 March 2012 and 14 March 2014.

59. The Agency states that it does examine whether registration dossiers for the same substance contain the information which may be missing from the registration dossier under evaluation. The Agency states that, in the present case, the registration dossiers for the same substance were checked during the examination of the testing proposal. The Agency adds, however, that at the time of this examination the other registrant had registered the substance at the 1 to 10 tonnes per annum tonnage band and that, since no reproductive toxicity studies were required at that tonnage band, no such information was contained in the other registrant's dossier.

60. The Agency claims that it assessed all information available to it up to the notification of the draft decision to the MSCAs for proposals for amendment. The Agency adds that the other registrant only included information on the OECD 421 screening study in its dossier on 24 June 2013 when it updated its dossier to the 10 to 100 tonnes per annum tonnage band. The Agency points out that this was after the date the MSC agreed to the test proposed by the Appellant and that therefore it was not available to the Agency during the relevant steps of the decision-making process.

61. The Agency states that it does not take into account any new information submitted in the registration dossier after the draft decision has been referred to the MSCAs for the submission of proposals for amendment. The Agency claims that the Appellant was clearly informed of this cut-off point in the notification letter of 7 January 2013 inviting the Appellant to comment on the draft decision. The Agency adds that this cut-off point for new information equally applies to dossier updates submitted by other registrants of the same substance. The Agency claims that, consequently, the Appellant could not entertain the legitimate expectation that an update of another dossier which was performed after the MSC had reached unanimous agreement on the draft decision would be taken into account in the final decision.

62. The Agency claims that if it were required to check for dossier updates until the time a decision is adopted this would create an unreasonable burden for it. The Agency claims that if it were to take into account information submitted after the MSC has reached a unanimous position it would breach the evaluation decision-making procedure set out in Articles 50 and 51. The Agency argues further that Article 25 does not impose upon it an additional duty to verify the pertinence of new information from other registration dossiers for the same substance during the entire decision-making process.

63. The Agency maintains that it has not breached the principle of proportionality as it assessed all the information available to it up to the notification of the draft decision to the MSCAs. Moreover, the Agency submits that the Appellant has not questioned the correctness of the Agency's assessment, undertaken on the basis of the available information, that the EOGRTS was necessary.

64. The Agency states that if the information from the other registrant's dossier is sufficient to remove the concern identified by the Appellant for the reproductive toxicity of the Substance, the Appellant will need to submit a justification to this effect in an updated registration dossier. The Agency adds that, pursuant to Article 42(1), after the deadline set in the Contested Decision the Agency will examine the information submitted in the updated dossier.

65. The Agency claims that in this case, pursuant to Section 1.1.4 of Annex I, faced with two tests with contradictory results the Agency would have, without an assessment of the reasons for the apparently contradictory results, still requested the EOGRTS as the Appellant's test results gave rise to the highest concern.

66. The Intervener argues that to ensure compliance with the last resort principle, set out in Article 25, the time the other registrant's screening study became available should not prevent the Agency from assessing this data prior to the deadline set in the Contested Decision. The Intervener claims that the Agency's approach, as set out in paragraph 64 above, puts the Appellant in a position of unacceptable legal uncertainty and will almost certainly lead to some registrants choosing to carry out tests rather than submitting justifications as to why such tests are not required.

67. The Intervener considers that the Agency should introduce some flexibility into its administrative procedures to deal with situations such as the one in the present case where new information comes to light prior to the deadline set in a particular Agency decision. The Intervener considers that such flexibility is particularly necessary when there is a possibility that unnecessary animal testing will be carried out.

Findings of the Board of Appeal

68. Essentially, the Appellant submits that in adopting the Contested Decision the Agency breached its obligation to take into account all available information, including information submitted as part of other registration dossiers for the Substance. Specifically, the Appellant claims that the Agency should have taken into account the OECD 421 screening study contained in the other registrant's dossier for the Substance which was submitted prior to the adoption of the Contested Decision.

69. The Board of Appeal notes that, in order to examine the concerns identified in the OECD 421 screening study conducted by the Appellant pursuant to Section 8.7.1 of Annex VIII, the Appellant itself proposed that it would perform an EOGRTS. The Board of Appeal finds that, in considering this proposal, at the time of the MSC meeting at which the draft decision requiring the EOGRTS was agreed, it was reasonable for the Agency to take the view, based on the information available to it, that the concern identified in the Appellant's OECD 421 screening study required further investigation. This has not been disputed by the Appellant.

70. The Board of Appeal also considers that, up until the time of the MSC agreement on the draft decision, the Agency had conducted its examination of the Appellant's testing proposal correctly. In particular, the Agency confirmed during the present proceedings that, in line with its practice at the time, it had examined whether other registration dossiers for the Substance contained relevant information. The Agency clarified further that the check of the other registration dossiers for the Substance occurred prior to the sending of the draft decision to the MSCAs for any proposals for amendment pursuant to Article 51(1). Until that point, the Agency's actions were therefore consistent with Section 2.1.6.1 of the Agency's Guidance on Dossier and Substance Evaluation (June 2007) which states inter alia that '*[i]n order to accomplish its tasks, the Agency should also check the information in other registration dossiers available for the same substance*'.

71. The Board of Appeal notes that the Agency has introduced a cut-off point in the decision-making process after which it will not take into account, for the purposes of its decision, any new information that comes to light. In this particular case, the cut-off point was the moment the draft decision was sent to the MSCAs for their proposals for amendment pursuant to Article 51(1).

72. The Board of Appeal observes that, prior to the MSC agreement of 13 June 2013 on the draft decision, the other registrant had registered the substance at the 1 to 10 tonnes per annum tonnage band. For registrations at this tonnage band, no reproductive toxicity studies are required for registration purposes, and the registration dossier of the other registrant at that time contained no such information. The other registrant's dossier update to the 10 to 100 tonnes per annum tonnage band, including its own OECD 421 screening study, was only submitted on 24 June 2013. In other words, the other registrant's OECD 421 screening study was submitted to the Agency after the MSC had reached an agreement on the draft decision on the Appellant's testing proposal but before the Contested Decision was adopted by the Agency. For the purposes of deciding on this plea, the Board of Appeal is therefore required to decide whether the Agency should have taken into account, for the purposes of the Contested Decision, the other registrant's OECD 421 screening study.

73. The Board of Appeal acknowledges that in its examination of the merits of a testing proposal pursuant to Article 40 the Agency has a wide discretion. Indeed the Agency's discretionary powers in general have been recognised by the European Union Courts which have held that '*[…] the Agency has a broad discretion in a sphere which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments*' (see Case T-96/10, *Rütgers Germany GmbH and Others* v *ECHA,* EU:T:2013:109, paragraph 134).

74. The fact that the Agency has a wide margin of discretion does not, however, prevent the Board of Appeal from examining whether the Agency, when exercising its discretion, took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (see, by analogy, Case T-96/10, *Rütgers Germany GmbH and Others* v *ECHA,* EU:T:2013:109, paragraph 100). In exercising its discretion the Agency is required to take into account and balance a number of, sometimes competing, considerations. For the purposes of the present case, those considerations included the need, pursuant to Article 25(1), to ensure that testing on vertebrate animals is undertaken only as a last resort, and the need for administrative efficiency.

75. With regards to the first of these considerations, the Board of Appeal observes that Article 25(1) provides that testing on vertebrate animals for the purposes of the REACH Regulation shall be undertaken only as a last resort. The Board of Appeal considers that the duty to avoid animal testing pursuant to Article 25(1) applies to the Agency, as well as to registrants, when it examines a testing proposal under Article 40.

In this regard, the Board of Appeal notes that the Agency's checks of the dossiers of other registrants of the same substance for relevant information is good practice and one practical way for the Agency to help ensure that, pursuant to Article 25(1), testing on vertebrate animals is undertaken only as a last resort.

76. With regards to the second of the considerations that the Agency must take into account, namely the need for administrative efficiency, the Board of Appeal notes that, as mentioned in paragraph 71 above, with the aim of ensuring efficiency in its dossier evaluation processes and to avoid an unreasonable burden, the Agency has introduced a cut-off point after which it will not take into account for the purposes of its decision any additional information that comes to light. The Board of Appeal notes that efficiency in the decision-making process means that a greater number of decisions can be adopted by the Agency, registrants can be informed of the results of evaluations more rapidly, and, as a consequence, registration dossiers can be brought into compliance with the requirements of the REACH Regulation at a faster rate. This in turn should result in benefits to the protection of human health and the environment.

77. According to the Agency, any information coming to light after the cut-off point will only be assessed by the Agency if the registrant includes it in a dossier update and even then not before the deadline defined in the decision requiring the information. In the present case, the dossiers of other registrants of the Substance were therefore not checked by the Agency after the draft decision was sent to the MSCAs for proposals for amendment. As a result, in the present case, the other registrant's OECD 421 screening study was not taken into consideration for the purposes of the Contested Decision.

78. The Board of Appeal observes that the cut-off point is not defined in the REACH Regulation. The Board of Appeal considers however that practices such as the setting of a cut-off point in a decision-making process may fall within the Agency's margin of discretion. In order to ensure that it has exercised its discretion correctly, however, the Agency must balance the need for administrative efficiency with other relevant considerations such as the need to ensure compliance with Article 25(1). The Board of Appeal will now examine whether the Agency took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate.

79. In examining whether the Agency should have taken into consideration the OECD 421 screening study contained in the other registrant's dossier, which came to light after the cut-off point, the Board of Appeal considers that the relevance of that information is an important consideration.

80. In this respect the Board of Appeal recalls that the OECD 421 screening study performed on the Substance by the other registrant was very similar, although not identical, to the one performed by the Appellant. Nonetheless, the two OECD 421 screening studies showed apparently contradictory results. The Board of Appeal notes that both screening studies appear to be reliable and that no assessment has yet been made of the reason for the apparently contradictory results and whether this may be a result of the different sub-strains of rats used, of the different vehicles used, of the differences in the substances tested, a combination of the above, or other reasons.

81. The Board of Appeal considers that if the results of both OECD 421 screening studies had been known this information might have changed the Appellant's conclusion that an EOGRTS was necessary. Equally, this information might have changed the Agency's conclusion regarding the proposed test, the comments of the MSCAs, and the MSC's agreement that the proposed test was required.

82. The Agency itself raised the possibility that the EOGRTS may not be needed as a result of the OECD 421 screening study contained in the other registrant's dossier in its letter of 14 March 2014 to the Appellant and the other registrant. In the letter to the

Appellant, for example, the Agency stated inter alia that the Agency recognises '… *that [the other registrant's] screening study may be relevant for your considerations on whether or not to perform the extended one generation study*'. Likewise, in its Defence the Agency acknowledges that the other registrant's '*…OECD 421 study may be relevant in the determination whether the test requested in the Contested Decision is necessary to clarify concerns for the reproductive toxicity hazard of the substance*'.

83. The Board of Appeal notes further that at the oral hearing the Appellant stated that it would not have made the testing proposal if it had known of the results of the OECD 421 screening study performed by the other registrant. Whilst it is not possible to know how the MSCAs or the MSC would have reacted if they had also been presented with the results of the other registrant's OECD 421 screening study, it cannot be ruled out that they would have changed their opinion on the need for an EOGRTS to be performed in the present case. The Board of Appeal notes that one MSCA provided observations on the draft decision to the effect that the results of the Appellant's OECD 421 screening study did not justify further testing, even before the results of the other registrant's screening study were known.

84. In view of the above, the Board of Appeal finds that the other registrant's OECD 421 screening study is clearly a relevant factor in the consideration of whether the EOGRTS proposed by the Appellant should be performed. The Board of Appeal considers that the results of the other registrant's OECD 421 screening study therefore constituted substantial new information that could potentially have influenced the Contested Decision as regards the need to perform the vertebrate animal study.

85. The Board of Appeal considers that the relevance of the other registrant's screening study to the evaluation of the testing proposal is not affected by the Agency's claim that, pursuant to Section 1.1.4 of Annex I, faced with two tests with contradictory results such as those in the present case, the Agency would have, without an assessment of the reasons for the apparently contradictory results, still requested the test as the Appellant's test results gave rise to the highest concern. The Agency argues that as the Appellant's study is the one giving rise to the highest concern it should normally be the study to be used for the Derived No-Effect Level ('DNEL') derivation and hazard and risk assessment. According to the Agency, this is the case unless the Appellant is able to provide full scientific justification in its registration dossier as to why the study demonstrating the higher concern is not being used for such purposes. According to the Agency, in this case the Appellant would need to include in its dossier both the study performed by the other registrant and its own study demonstrating a higher concern.

86. The Board of Appeal however observes that if information on the OECD 421 screening study performed by the other registrant had been available and the results thereof assessed and included in the draft decision by the Agency, then the Appellant, the MSCAs and the MSC would have had the opportunity to comment on its relevance and importance which in turn might have led to a different decision. In particular, if the Agency had brought this information forward the Appellant might have been able to provide a justification as to why the other registrant's OECD 421 screening study has removed the concern identified in the Appellant's own study.

87. The Board of Appeal also accepts that, in the present case, before the draft decision was sent to the MSCAs for their proposals for amendment the Appellant was not aware of the other registrant's intention to perform the OECD 421 screening study or the results thereof. It was therefore not possible for the Appellant to update its own registration dossier with this information or to bring the issue to the Agency's attention prior to the cut-off point.

88. Having established that the other registrant's OECD 421 screening study was substantial new information and a relevant factor in the examination of the Appellant's testing proposal, the Board of Appeal will examine the Agency's arguments that the administrative burden created by the examination of such information justifies the Agency not taking it into account when it comes to light after the Agency's cut-off point.

89. The Agency claimed during the present proceedings that the cut-off point in the decision-making process is essential to ensure the efficiency of that process. The Agency claimed, for example, that if it is required to perform checks of information submitted after the draft decision was sent to the MSCAs, this would render its work unmanageable. The Agency argues in particular that if it is required to take into account new information after this point it would be required to restart the decision-making process which would significantly increase the number of new decision-making processes, delay the decision-making process itself, and reduce the number of final decisions taken. The Agency acknowledged at the hearing that there is no legal obstacle to restarting the decision-making process in such circumstances.

90. The Board of Appeal acknowledges that if the Agency is required to examine all information coming to light after the draft decision has been sent to the MSCAs it will require the use of resources by the Agency to decide on the pertinence of that information to the examination of testing proposals. Furthermore, the Agency may, depending for example on the relevance and importance of any new information, be required to restart the decision-making process laid down in Articles 50 and 51. This might be necessary in some cases to ensure that all the relevant actors are given the opportunity to comment on that information. This would inevitably entail additional work for the Agency and all those involved in the decision-making process and would delay the adoption of decisions.

91. The Board of Appeal considers, however, that the administrative burden alone cannot justify the Agency's departure from the obligations incumbent upon it. The extent of the administrative burden placed on the Agency must also be taken into consideration. The Board of Appeal will therefore examine whether the administrative burden placed on the Agency would be sufficiently excessive to justify, in the interests of administrative efficiency, a departure from the obligations placed on it pursuant to Article 25(1).

92. During the present proceedings the Agency itself acknowledged that the likelihood of a new study repeating an earlier study and giving apparently contradictory results coming to light after the cut-off point is extremely limited. The Board of Appeal also considers that such situations should be rare as there are other mechanisms in place, for example the provisions on data sharing, that help to prevent this. The Board of Appeal also notes that the likelihood of such information coming to light between the time the draft decision is sent to the MSCAs and the final adoption of the decision by the Agency would be further reduced the shorter the time between the MSC agreement and the adoption of the Contested Decision. In the present case there was a four month period between the MSC agreement and the Agency's adoption of the decision.

93. The Agency also claims that the administrative burden resulting from an obligation to check for updates in other dossiers after the cut-off point and until the decision in question is adopted would be unreasonable. The Board of Appeal notes, however, that the Agency has not demonstrated that this is anything other than a hypothetical problem. The Board of Appeal observes that for a testing proposal it should be a relatively straight forward task for the Agency, using the IT-systems in place, to check for the relevant endpoint whether other registration dossiers for the same substance contain relevant new information.

94. In the circumstances of this particular case, the Board of Appeal finds that the Agency has failed to establish that the requirement to check other registration dossiers for the same substance and subsequently take into account any new information found as a result is an excessive administrative burden. This argument is therefore rejected.

95. The Board of Appeal will also consider the Agency's other arguments for not taking into account the OECD 421 screening study contained in the other registrant's dossier for the purposes of the Contested Decision on the grounds that it only became available to the Agency after the cut-off point.

96. The Agency argued during the present proceedings that the problems presented in this case were created by the Appellant's own failings with regards to its obligations to submit a joint registration and share data with the other registrant. The Board of Appeal also considers that there may have been shortcomings in the Appellant's interactions with the other registrant. For example, on 27 September 2012, further to the inquiry process, the Appellant informed the other registrant via email that it owns data on '*OECD 412 and 425*'. However, on 8 February 2013, the Appellant corrected this statement by informing the other registrant that in fact instead of an '*OECD 412*' study it owned an '*OECD 421*' study. More efficient communication and coordination between the Appellant and the other registrant may have meant that the other registrant's OECD 421 screening study would not have been conducted in the first place.

97. The Board of Appeal considers, however, that the Appellant's potential failings in this case do not relieve the Agency of its own obligations with regard to the need for animal testing to be a last resort pursuant to Article 25(1). The Board of Appeal will not therefore examine further the Agency's arguments regarding the Appellant's breach of the provisions of the REACH Regulation on joint submissions and data sharing. The Board of Appeal also notes that any alleged failings by the Appellant with respect to data sharing and joint submission obligations may be subject to separate actions by the appropriate authorities.

98. The Agency also claims that it does not need to take into account in the decision-making process information received after the cut-off point since, in any case, it will examine such information, if included in an updated registration dossier, after the deadline set in the decision requesting the information. The Agency stated further during the proceedings that if the information provided by the Appellant in an updated dossier complies with the Contested Decision, either by submitting the requested test or a valid explanation as to why the test is no longer needed, the Agency will, in accordance with Article 42(2), notify the Commission and the MSCAs of the information received and any conclusions made. According to its current practice, if the Agency considers that the information provided by the Appellant does not comply with the Contested Decision, the Agency will inform the relevant MSCAs accordingly and invite them to take appropriate action.

99. The Agency also stated, for example in its letter to the Appellant of 22 November 2013, that '*[i]n line with its standard policy…[the Agency] cannot provide any scientific advice or comments on any alternative strategies or approaches that the registrant considers to use to fulfil the request in the decision, [the Agency] expects the requested information specified in the decision is provided by the deadline set and will evaluate the updated dossier in line with Article 42(1) … after the deadline has passed*.'

100. In the present case, and according to the Agency's current practice, if the Appellant considers that the other registrant's OECD 421 screening study is sufficient to remove the concern identified by the Appellant and that no further testing is required it could include this information in an updated registration dossier justifying why the proposed test is no longer needed. The Appellant would then, however, have to wait until after

the expiry of the two year deadline set in the Contested Decision for the Agency to carry out its assessment of that information. This assessment would lead to the Agency either confirming that no further testing was required or issuing a statement of non-compliance indicating that the Appellant had failed to satisfy the information requirement, potentially resulting in enforcement action at the Member State level. The Board of Appeal considers that this situation leaves registrants in a state of considerable uncertainty. The fact that such actions may create difficulties for registrants is recognised in the Agency's Fact Sheet on follow-up to dossier evaluation decisions (ECHA-13-FS-05-EN, October 2013) which states that '*registrants may, under their own responsibility and risk, decide to fulfil the information requirements in an alternative way than requested in the decision...*'. Such uncertainty, the 'risk' referred to above, may lead registrants, in order to comply with an Agency decision which is not based on all the information available at the time the decision was adopted, to perform tests on animals to be certain that they are acting in compliance with a decision addressed to them.

101. The Board of Appeal finds that the Agency's refusal to re-examine its findings in the light of new information received after the cut-off point has passed, and before the deadline set in the Contested Decision, potentially risks, contrary to Article 25(1), the duplication of tests on vertebrate animals, solely to ensure compliance with an Agency decision.

102. The Board of Appeal notes that the Agency's approach to taking into account information that comes to light after the draft decision is sent to the MSCAs might also, in other cases, have a detrimental effect on the other objectives of the REACH Regulation. For example, if a serious concern to human health is identified from a study included in another dossier for the same substance after the draft decision had been sent to the MSCA, the Agency should be able to take that into account in its decision-making. In other words, the early assessment of information coming to light after the draft decision is sent to the MSCAs and before the adoption of a decision can also serve the objectives of the protection of human health and the environment.

103. In light of all of the above, the Board of Appeal finds that the Agency did not have in place a suitable mechanism for dealing with substantial new information that was unknown to the Appellant prior to the cut-off point and was submitted to the Agency after its cut-off point but before the Contested Decision was adopted. The Agency's procedures in this respect were too rigid and led to the situation where the Contested Decision was adopted without taking into account substantial new information available prior to its adoption. This failure could have resulted in the unnecessary use of a substantial number of animals and associated costs.

104. The Board of Appeal therefore finds that, in the present case, the Agency should have taken into account in the decision-making process leading to the adoption of the Contested Decision the other registrant's OECD 421 screening study. In the particular circumstances of this case, the Agency's strict application of the cut-off point, on the grounds of administrative efficiency, was too inflexible. The Agency did not, in this particular case, take account of all the relevant facts and circumstances in balancing the need for administrative efficiency with the obligations placed on the Agency pursuant to Article 25(1). As a result, the Board of Appeal finds that the Agency's decision was in breach of Article 25(1) insofar as it did not take account of all the relevant circumstances in applying that Article. The Contested Decision should therefore be annulled and the case remitted to the Agency for further action.

105. The Board of Appeal also considers that, since the Board of Appeal has found in paragraphs 43 to 48 above that the Agency did not make an error in conducting the third party consultation, the Agency is not required to repeat the third party consultation provided for in Article 40(2) in this case. In a re-examination of the

Appellant's testing proposal and the preparation of any draft decision, however, the Agency should take into consideration the OECD 421 screening study available in the other registrant's dossier. As a result, the Agency should recommence the decision making process provided for in Articles 50 and 51. Whilst the Agency may still conclude that the EOGRTS is required, this will allow the Appellant, the MSCAs and, if necessary the MSC, the opportunity to comment and, with respect to the latter, eventually agree on the decision in the light of all the information available at the time the decision is adopted. This is without prejudice to any obligations that may apply to the Appellant and the other registrant pursuant to Article 22(1).

106. Since the appeal has been upheld, the Board of Appeal does not need to examine the arguments related to legitimate expectations resulting from the Agency's guidance.

Refund of the appeal fee

107. 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 Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (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.

108. As the Board of Appeal has decided the appeal in favour of the Appellant in the present case, the appeal fee shall be refunded on that basis.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls Decision TPE-D-0000003219-74-05/F adopted by the European Chemicals Agency on 15 October 2013.**

2. **Remits the case to the competent body of the Agency for re-evaluation of the Appellant's testing proposal.**

3. **Orders the refund of the appeal fee.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal