EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

7 October 2016

(Dossier evaluation – Compliance check of a registration – Pre-natal developmental toxicity study – Read-across adaptation – Duties of the Agency)

Case number	A-017-2014
Language of the case	English
Appellant	BASF SE, Germany
Intervener	PETA International Science Consortium Ltd, United Kingdom
Contested Decision	CCH-D-0000004930-75-04/F of 19 September 2014 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 41(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 17 December 2014, the Appellant lodged the present appeal at the Registry of the Board of Appeal against the Contested Decision. The Contested Decision requests the Appellant to submit, inter alia, a pre-natal developmental toxicity study in rats or rabbits by the oral route, following test method EU B.31/OECD 414 (hereinafter the 'PNDT study') on the Appellant's registered substance in order to fulfil the information requirements of Section 8.7.2 of Annex IX to the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless otherwise stated).

Background to the dispute

2. On 22 November 2013, the Agency notified to the Appellant a draft decision following a compliance check of its registration dossier for the substance prop-2-yn-1-ol (CAS No 107-19-7, EC No 203-471-2; hereinafter the 'Substance') pursuant to Article 41(1) (hereinafter the 'Draft Decision'). The Contested Decision was based on the registration as submitted for the tonnage band of 1000 tonnes or more per year. The Draft Decision required, inter alia, that the Appellant submit a PNDT study for the Substance in order to fulfil the information requirements of Section 8.7.2 of Annex IX.

3. The Agency noted in the Draft Decision that the Appellant, in order to address this standard information requirement, proposed an adaptation based on a read-across from the analogue substance 2-butyne-1,4-diol (hereinafter the 'read-across substance') on the basis of a PNDT study conducted in rats on the read-across substance supported by a reproduction and developmental toxicity screening test, following test method OECD 421 (hereinafter the 'screening test') conducted on the Substance (hereinafter the 'read-across proposal').

4. The Agency stated in the Draft Decision that, concerning the PNDT study on the read-across substance and the screening test on the Substance, '*[the Appellant] has supported the read-across approach stating that the results obtained from the [PNDT study] performed with the [read-across substance] are in line with the results obtained from [the screening test] performed with the [Substance]. However, while the oral gavage dosing in the pre-natal developmental toxicity study was possible up to 80 mg/kg bw/day with only one death observed after 10 days treatment, in the screening test three animals died at the dose 45 mg/kg bw/day, administered via oral gavage within a week. Therefore, [the Agency] notes that the registered substance seems to be more toxic than the [read-across] substance.*' The Agency added that '*[the screening] study does not cover key parameters of a pre-natal developmental toxicity study like examinations of foetuses for skeletal and visceral alterations'.*

5. The Agency added in the Draft Decision, when assessing whether the read-across proposal met the criteria in Section 1.5 of Annex XI on grouping of substances and read-across approach, that '*the Registrant has not supported the read-across argument with any quantitative comparison of the toxicological properties of the two substances, including a consideration of the above-mentioned indications of a higher toxicity of the registered substance than the analogue substance*'.

6. The Agency indicated in the Draft Decision that the deadline for the Appellant to submit comments on it was 23 December 2013. The Draft Decision also indicated that

'*the enclosed draft decision still has to be processed further pursuant to Articles 50(1) and 51 […] before becoming a binding decision: First, [the Agency] will consider the comments you submit in the commenting period and possibly amend the draft decision accordingly. Then, [the Agency] will notify the Member State Competent Authorities of the [Draft Decision] and they can propose amendments within 30 days. If no proposals for amendments are received from the Member State competent Authorities, [the Agency] will take the decision. If proposals for amendments are received from the Competent Authorities, the draft decision will be referred to the Member State Committee for taking the decision.*' The cover page of the Draft Decision also indicated that '*in order to follow the procedure outlined in Articles 50(1) and 51 [...], [the Agency] will not take into consideration any update of the dossier received after the date on which Member State Competent Authorities are notified of the [Draft Decision] in accordance with Article 51(1)'.*

7. On 20 December 2013, within the deadline given, the Appellant submitted comments on the Draft Decision. The Appellant stated that '*[it could not be concluded] that the toxicity of one substance is superior as compared to the other'* and included a table summarising '*the toxicological profiles and some physico-chemical properties*' of the Substance and the read-across substance (hereinafter the 'first comparison table'). The Appellant also updated its registration dossier on the same day, with a '*justification for the read-across approach using the reporting format for analogues according to the Guidance on information requirements and chemical safety assessment, chap. R.6.2.6.*'. This update included a '*detailed read-across justification document*' (hereinafter the 'first justification document') and a table comparing the Substance and the read-across substance (hereinafter the 'first dossier update'). The Agency considered the Appellant's comments on the Draft Decision and the first dossier update and revised certain elements of the Draft Decision (hereinafter the 'modified Draft Decision') but maintained the requirement for a PNDT study.

8. On 6 March 2014, the Agency notified the modified Draft Decision to the competent authorities of the Member States (hereinafter the 'MSCAs') in accordance with the procedure laid down in Article 51(1). The Agency received several proposals for amendment pursuant to Article 51(2). One of the proposals for amendment proposed to remove the request for the PNDT study on the basis that the read-across proposal should be accepted (hereinafter the 'PfA').

9. On 10 April 2014, the Agency notified the proposals for amendment to the Appellant and invited it to comment on them pursuant to Article 51(5).

10. On 12 May 2014, the Appellant submitted new comments to the Agency. The cover page to these comments was entitled '*registrants comments concerning the draft decision on a compliance check under [the REACH Regulation] - receipt of proposals for amendments from [MSCAs] - for [the Substance]'*. In its comments, the Appellant explained that it acknowledged in particular the PfA. On the same day, the Appellant submitted to the Agency a further update of its registration dossier (hereinafter 'the second dossier update'). In the second dossier update, the Appellant included in support of the read-across proposal a robust study summary for a subacute toxicity study following test method OECD 407 conducted on the read-across substance and a robust study summary for a 90-day subchronic toxicity study on the Substance. The Appellant also updated the first comparison table (hereinafter the 'second comparison table') comparing the Substance and the read-across substance, integrating information on specific target organ toxicity (hereinafter 'STOT') and the text of the first justification document (hereinafter the 'second justification document').

11. Between 10 and 13 June 2014, the Member State Committee (hereinafter the 'MSC') met and agreed to modify certain sections of the modified Draft Decision concerning information requirements not contested by the Appellant but maintained the requirement for the Appellant to perform a PNDT study and did not amend the section of the Statement of Reasons relating to the PNDT study. On 12 June 2014, pursuant to Article 51(6), the MSC agreed unanimously on the Contested Decision, which was subsequently adopted by the Agency.

12. On 19 September 2014, the Agency notified the Contested Decision to the Appellant. The Contested Decision required the Appellant to submit the results of the PNDT study within twelve months and seven days from the date of its adoption.

Procedure before the Board of Appeal

13. On 17 December 2014, the Appellant lodged the present appeal.

14. On 11 March 2015, PETA International Science Consortium Ltd (hereinafter 'PISC') applied to intervene in the proceedings in support of the Appellant. On 21 October 2015, the Board of Appeal, having heard the Parties, granted PISC's application.

15. On 19 March 2015, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.

16. Following consultation with the Parties, the appeal proceedings were stayed between 9 June 2015 and 1 September 2015 in accordance with Article 25 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').

17. On 17 September 2015, since the position of legally qualified member of the Board of Appeal was vacant and in order to achieve the full composition of the Board of Appeal, the Chairman, pursuant to the first subparagraph of Article 3(2) of the Rules of Procedure, designated an alternate member, Sakari Vuorensola, to act in the present case as the legally qualified member of the Board of Appeal.

18. On 14 January 2016, PISC submitted its statement in intervention.

19. On 12 February 2016, the Appellant lodged observations on the Agency's Defence. On 8 April 2016, the Agency submitted observations on the Appellant's observations on the Defence.

20. On 24 February 2016, the Appellant and the Agency submitted their observations on the Intervener's statement in intervention.

21. On 8 March 2016, the Board of Appeal submitted a list of written questions to the Appellant and to the Agency. The Appellant responded to the questions of the Board of Appeal on 5 April 2016.

22. On 8 April 2016, the Agency submitted its observations on the Appellant's observations on the Agency's Defence and responded to the questions of the Board of Appeal.

23. On 19 May 2016, the Parties were notified of the Board of Appeal's decision to close the written procedure.

24. On 25 and 27 May 2016 respectively, the Appellant and the Agency informed the Board of Appeal that they did not request a hearing to be held in the present case.

Reasons

25. In support of its appeal, the Appellant raises four pleas in law which are addressed in turn below.

The first plea, alleging a breach of Articles 50(1) and 51(5)

Arguments of the Parties

26. By its first plea, the Appellant contends that the Contested Decision is illegal as it was taken in violation of Articles 50(1) and 51(5). The Appellant argues in particular that its comments submitted on the modified Draft Decision were not taken into account. The Appellant adds that the Agency has the obligation pursuant to Articles 50(1) and 51(5) to take any comments received from any registrants and downstream users concerned into account consequent to PfAs being communicated to them and that this obligation is not limited to the mere acknowledgment of the receipt of such comments. The Appellant also argues that by breaching these provisions, the Agency did not respect the Appellant's right to be heard as it was not given the possibility to influence the decision-making process leading to the adoption of the Contested Decision. The Appellant further argues that it had legitimate expectations that substantial comments it made in the course of the procedure laid down in Article 51 would be assessed by the authorities in a professional and scientific way.

27. The Appellant also argues that the statement made in the Contested Decision that '*[t]he Member State Committee took the comments […] of the [Appellant] into account'*, does not allow it to know whether its comments were assessed and if its rights under Articles 50(1) and 51(5) were respected.

28. The Appellant contends further that the Agency breached Articles 50(1) and 51(5) by ignoring several times during the dossier evaluation procedure the Appellant's arguments concerning STOT data. The Appellant argues that it included, on 20 December 2013, data on STOT in its comments on the Draft Decision and in its first dossier update. The Appellant adds further that this information was also contained in the registration dossier it submitted for the read-across substance, of which the Appellant is also a registrant, and in the second comparison table. This information was not assessed by the Agency.

29. The Appellant argues additionally that it justified its read-across proposal based on the structural similarity of the Substance and the read-across substance in line with the requirements of Section 1.5 of Annex XI. The Appellant adds that this approach was supported in the PfA which concluded that a toxicokinetic analysis was not required for the Substance as the read-across was based on '*structural similarity and not similar metabolism'*. The Appellant argues that the Agency was required to assess the read-across proposal based only on the structural similarity of the two substances but nevertheless rejected the read-across proposal for lack of metabolic or toxicokinetic data.

30. The Appellant argues further that the Agency failed to take into account the Appellant's comments in their entirety at the different stages of the evaluation procedure. The Appellant adds that it had a legitimate expectation that these comments would be assessed.

31. The Appellant adds that its arguments in support of the read-across proposal were not new at the time of its comments on the modified Draft Decision. The Appellant explains that information on structural similarity had already been submitted in previous versions of the registration dossier as well as in the comments on the Draft Decision. The Appellant further adds that structural similarity between the Substance and the read-across substance had also been pointed out in the PfA. The Appellant concludes that information on structural similarity was not new and should have been taken into account by the Agency. The Appellant also argues that its comments on the modified Draft Decision amounted to a change of factual circumstances within the meaning of Article 50(3) and that the Agency should therefore have taken them into account. In the Appellant's view, the Agency's refusal to re-examine its findings in the light of new information received after a draft decision is notified to the MSCAs also contradicts paragraphs 87, 89 to 91 and 101 to 103 of the decision of the Board of Appeal of 10 June 2015 in Case A-001-2014, *CINIC Chemicals Europe.*

32. The Appellant further argues that the Agency's policy not to take into account any registration dossier updates after a draft decision has been referred to the MSCAs is flawed and unlawful. In support of this argument, the Appellant claims that Article 51(5) does not place limits on the number and forms of communications that should be taken into account by the MSC as it refers to '*any comments received [from registrants or downstream users]*'.

33. The Agency argues that, while it is true that the section of the statement of reasons in the Contested Decision does not directly address the PfA or the Appellant's comments on it, the PfA is mentioned in the section of the Contested Decision describing the procedure leading to its adoption. The Agency explains further that there was no need to address the PfA in the statement of reasons in the Contested Decision as it had not been accepted by the MSC. The Agency adds further that the Contested Decision reflects the agreement of the MSC based on the registration dossier as it stood on 6 March 2014. The Agency also stated in the Contested Decision that '*[t]his decision does not take into account any updates submitted after 6 March 2014, the date upon which ECHA notified its draft decision to the [MSCAs] pursuant to Article 51(1)'.* In support of its argument, the Agency also relies on the public minutes of the MSC meeting of 10 to 13 June 2014 which explain that the additional arguments in support of the read-across proposal, and registration updates, submitted after the start of the MSCA consultation could not be taken into account in the decision-making process. The Contested Decision therefore had to be based on the first dossier update made by the Appellant on 20 December 2013. The Appellant's second dossier update of 12 May 2014 could not be taken into account, as it happened after 6 March 2014.

34. The Agency adds further that the Appellant had '*ample opportunity to present a compliant read-across argumentation'.* The Agency explains that the Appellant could have done so in its initial registration or in a dossier update after the receipt of the Draft Decision and before its referral to the MSCAs. The Agency also states that '*[t]he Contested Decision however had to be based on the version of the dossier as it stood at the time of referral to the MSCAs to ensure the efficiency of the evaluation process and that the strict deadlines of Article 51 REACH can be adhered to. Basing the decision on the registration as it stands at the time of MSCA referral also protects the rights of the Member States and the registrant, because it ensures that they can comment on the same draft decision that addresses the registration dossier with the contents that it had at the same point in time*'. The Agency adds that the MSC inserted a note in the Contested Decision to the effect that the Appellant can apply a read-

across approach to satisfy the information requirement for a PNDT study on the basis that it fulfils the conditions of Annex XI.

35. Concerning the STOT data, the Agency explains that it analysed this aspect on the basis of the first comparison table and the Appellant's comments on the Draft Decision. The Agency explains that although it did not take into account the second dossier update and the second justification document, it did take into account the first justification document included in the first dossier update and the comments on the Draft Decision and that these did not contain the necessary information to meet the requirements of Section 1.5 of Annex XI. The Agency concludes therefore that it did not breach Articles 50(1) and 51(5) when considering the STOT data in the Appellant's dossier.

36. Responding to the Appellant's argument that the read-across proposal based on structural similarity and supported by the PfA was not taken into account in the Contested Decision, the Agency explains that, in line with Articles 41(3), 50 and 51, the MSC did not accept the PfA and that the MSC did not consider the Appellant's modified read-across approach set-out in the second dossier update. The Agency adds further that Articles 22, 41, 42, 50 and 51 do not require it to evaluate a registration update after a compliance check has been initiated but that the Agency nevertheless takes into account dossier updates made before draft decisions are referred to the MSCAs. The Agency explains that the REACH Regulation does not impose procedural deadlines for the Agency to refer draft decisions to the MSCAs. However, as the REACH Regulation imposes strict deadlines after these referrals, it is impossible for the Agency to consider dossier updates once a draft decision is referred to the MSCAs. The Agency adds that this is explained in the Practical Guide 12 entitled '*How to communicate with ECHA in dossier evaluation*' (Version 1.1, July 2015). The Agency explains that, following the decision of the Board of Appeal of 1 August 2013 in Case A-003-2012, *Thor*, draft decisions now include a communication to registrants that updates made after referral of draft decisions to the MSCAs are not taken into account. The Agency concludes that it did not breach Articles 50(1) and 51(5) as the Appellant was made aware that dossier updates made after referral of a draft decision to the MSCAs are not taken into account.

37. The Agency adds that the second dossier update further substantiated the read-across proposal suggested by the Appellant in line with the PfA and provided more data comparing the Substance and the read-across substance. The update also included amongst others a robust study summary for a repeated dose toxicity study following test method OECD 407 on the read-across substance and a toxicokinetics study with the Substance which were not available, and merely referred to, in the earlier versions of the dossier. The Agency states that the read-across proposal in the second dossier update contained elements and data that could have been made available earlier by the Appellant.

Findings of the Board of Appeal

38. The Board of Appeal observes that the Appellant's first plea concerns a series of submissions which the Appellant made at different points in time during the decision-making process following a compliance check. The Board of Appeal observes that the Appellant's arguments concern primarily the submission of comments on the modified Draft Decision. However, as explained in paragraph 7 above, the Appellant also submitted comments on the Draft Decision. The Board of Appeal notes that the

Appellant's arguments sometimes lack clarity as to whether they concern its comments on the Draft Decision or on the modified Draft Decision. The Board of Appeal will therefore address, as necessary, the Appellant's comments on the Draft Decision and on the modified Draft Decision.

39. The Board of Appeal notes that the Appellant raised, in essence, five arguments in support of the first plea. First, the Appellant claims that Articles 50(1) and 51(5) oblige the Agency to take any comments received into account subsequent to PfAs being communicated to it and that the Agency breached these provisions by merely acknowledging the Appellant's comments on the Draft Decision and the modified Draft Decision. In a second argument, the Appellant contends that it had legitimate expectations that all of its comments would be assessed in their entirety by the authorities in a professional and scientific way. The Appellant repeats this argument as regards the merits of the structural similarity approach in the read-across proposal. Third, the Appellant claims that the Agency ignored its comments on STOT data in the dossier evaluation procedure and in particular the updated information in the second comparison table. In a fourth argument, the Appellant contends that Articles 50(1) and 51(5) were breached by the Agency by not taking into account the PfA. And fifth, the Appellant claims that the Agency's practice not to take into account comments and dossier updates submitted by registrants after the referral of draft decisions to MSCAs is flawed and unlawful.

40. Concerning the Appellant's first argument, the Board of Appeal considers it necessary to examine first whether the REACH Regulation provides registrants with a right to comment on the different versions of draft decisions during a compliance check procedure and particularly following the communication of PfAs to registrants.

41. The Board of Appeal recalls that Articles 50(1) provides that *'[t]he Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 46) and the Agency (for decisions taken under Articles 40 and 41) shall take any comments received into account and may amend the draft decision accordingly*.'

42. Article 50(1) does not oblige the Agency to request comments from the concerned registrants on all amended drafts following the first draft of a compliance check decision. When read in context, it is evident that the words '*any draft decision*' in Article 50(1) refer to draft decisions adopted under Articles 40, 41 or 46, which is to say draft decisions concerning the examination of testing proposals, the compliance check of registrations and requests for further information during the course of substance evaluation. Article 41(3) in particular provides that, on the basis of an examination of the information provided upon registration, the Agency may '*prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51*.' There is nothing in Articles 41 and 50(1) to suggest that the Agency is required, under those provisions, to invite registrants to comment on subsequent revised versions of a draft decision.

43. The Board of Appeal notes that Article 51(1) provides that '*[t]he Agency shall notify its draft decision in accordance with Articles 40 or 41, together with the comments of the registrant, to the competent authorities of the Member States*'. This provision must be read in conjunction with Articles 41(3) and 50(1) (see paragraphs 41 and 42 above), to the effect that the Agency shall notify its draft decision, modified if necessary in light of the comments submitted by the registrant, to the MSCAs.

44. In accordance with Article 51(2), '*[w]ithin 30 days of circulation, the Member States may propose amendments to the draft decision to the Agency*'. In accordance with Article 51(5), '*[t]he Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account*.' Contrary to the Appellant's claim, these provisions must be understood as giving the Appellant the opportunity to comment on any proposals for amendment to the draft decision and not once more on the draft decision itself (see Case A-009-2014, *Albemarle Europe and Others*, Decision of the Board of Appeal of 12 July 2016, paragraph 222 and the decisions cited therein).

45. The Board of Appeal finds therefore that it is not the objective of Articles 50(1) and 50(5) to allow a registrant to comment repeatedly on the Agency's assessment, as set out in successive drafts of the decision. Indeed, if the Appellant's argument was accepted and comments were to be requested after every revision of a draft decision, in light of the registrant's previous comments, the evaluation procedure could potentially develop into an endless commenting exercise.

46. In the present case, the Appellant was given a possibility to comment on the Draft Decision pursuant to Article 50(1) as well as on the PfAs submitted by the MSCAs pursuant to Article 51(5). The Board of Appeal therefore finds that the Agency did not depart from the procedure set up by the legislator in the evaluation title of the REACH Regulation.

47. The Appellant claims further under the first argument of the first plea that its comments on the Draft Decision and on the modified Draft Decision were merely acknowledged by the Agency and not taken into account. The Board of Appeal will consider first the comments submitted on 20 December 2013 on the Draft Decision and secondly those submitted on 12 May 2014 on the modified Draft Decision.

48. The Board of Appeal recalls that the Draft Decision stated, inter alia, that a PNDT study was needed to fulfil the standard information requirement in Section 8.7.2 of Annexes X and XI. The read-across proposal provided by the Appellant in its registration dossier was considered by the Agency to be insufficient. The Agency identified in the Draft Decision three deficiencies in the Appellant's dossier for the PNDT endpoint. Firstly, the screening test did not cover the key parameters of a PNDT study and especially the examination of foetuses for skeletal and visceral alterations. Secondly, the PNDT study performed by the Appellant on the read-across substance and the screening test performed on the Substance showed that the Substance seemed to be more toxic than the read-across substance because the PNDT study performed by the Appellant on the read-across substance showed only one animal death after ten days whilst the screening test on the Substance showed three deaths after a week at a lower dosage. And thirdly, the Agency noted that the read-across proposal was not supported with a quantitative comparison of the physical-chemical properties of the two substances nor with a systemic comparison of their toxicological properties.

49. The comments submitted by the Appellant on the Draft Decision included the first comparison table *'[summarising] the toxicological profiles and some physico-chemical properties of [the Substance] and [the read-across substance]'.* Drawing on the first comparison table, the Appellant concluded that the Substance and the read-across substance *'show similar toxicological characteristics'* and that the Substance is *'characterized by a potent systemic toxic behaviour following repeated administration'.* The Appellant explained further that it *'inserted a detailed read-across justification document in the updated dossier explaining the toxicological characteristics of the two substances'.*

50. In the modified Draft Decision, the Agency reiterates the need for a PNDT study and the three deficiencies already identified in the Draft Decision (see paragraph 48 above). In addition, the modified Draft Decision addresses the Appellant's justification of the read-across proposal in the first dossier update and its comments on the Draft Decision by explaining that *'from the table comparing the toxicological profiles of the two substances, it is not clear whether liver, kidney and spleen/blood cell toxicity occurs at the same dose levels with the same severity for both substances in repeated dose toxicity studies, thus allowing to conclude that the potency would be about the same related to systemic toxicity organ by organ'.* The modified Draft Decision also states that the read-across proposal is based on structural similarity and *'is not substantiated with comparison of any metabolic or toxicokinetic data available on the two substances'.* The Agency also adds that *'the REACH Regulation does not contain generic provision to adapt the standard information requirement of the [PNDT] study if the substance shows a potent systemic toxic behaviour following repeated administration'.* The Board of Appeal finds therefore that the first dossier update and the comments made by the Appellant on the Draft Decision were addressed and taken into account by the Agency and that, on the basis of the content of the modified Draft Decision, this was done in a professional and scientific manner. The Agency therefore correctly fulfilled its obligations under Articles 50(1) and 51(5).

51. Whilst not decisive in the present case, in light of the finding of the Board of Appeal in the previous paragraph, the Board of Appeal will briefly examine the Appellant's claim that its comments on the modified Draft Decision were merely acknowledged by the Agency. Following notification of the PfAs, the Appellant commented on the modified Draft Decision stating inter alia that *'[the Appellant] acknowledges the acceptance of the read-across from [the read-across substance] to the [Substance] as well as the [PfA] to remove the request for a [PNDT] study from Section II of the [Draft Decision]'.*

52. The Appellant further included in this set of comments references to robust study summaries for the read-across substance on a repeated dose 28-day oral toxicity study following test method OECD 407, and a 90-day subchronic toxicity study conducted with the Substance as well as further justification for the proposed read-across and a *'scientifically robust justification for waiving the conduction of a [PNDT] study on a second species'.* After summarising the results of these studies, the Appellant concluded that *'these data clearly underline the structural similarity and toxicological comparability of the two substances. Since the read-across is clearly based on structural similarity and not similar metabolism, as also indicated [in the PfA], [the Appellant] will not consider any toxicokinetic analysis to be required.'* The Board of Appeal notes that by this statement, the Appellant, rather than addressing the deficiencies outlined by the Agency, sought to confirm its earlier approach largely on the basis of the PfA.

53. The Board of Appeal observes that the Contested Decision states that '*[the MSC] took the comments on the [PfAs] of [the Appellant] into account. [The MSC] did not take into account [the Appellant's] comments on [the modified Draft Decision] as they were not related to the proposals for amendment made and are therefore considered outside of the scope of Article 51(5)'*. The PfA stated that the MSCA in question disagreed with the Agency's conclusion rejecting the read-across proposal. The assessment of the PfA is implicitly reflected in the public minutes of the MSC meeting of 10 to 13 June 2014. These minutes state that '*[i]t* was *considered that when submitting a testing proposal a plausible read across approaches may be substantiated with future testing results, however, this would not apply to compliance checks where there has to be sufficient justification and documentation in the registration dossier when adapting an information requirement. Also, considering that for this substance a data gap may exist for the second species PNDT test*, *the MSC agreed unanimously on the [Draft Decision] (part B) addressing the first species, PNDT information requirement by requesting a test with the registered substance (part B) as modified during the meeting*'.

54. The Board of Appeal notes that, as stated at paragraph 10 above, the Appellant, when invited to comment on the PfAs pursuant to Article 51(5), did so in a document that provided comments both on the modified Draft Decision and the PfAs. In these comments the Appellant commented primarily on the modified Draft Decision but largely centred its arguments on the content of the PfA to support its read-across proposal.

55. The Board of Appeal has already found in paragraphs 40 to 46 above that, in the present case, the Agency had no legal obligation to examine the comments of the Appellant on the modified Draft Decision. However, the Board of Appeal observes that the Agency, in examining the Appellant's comments on the PfA and the PfA itself (see paragraph 53), did examine the essence of the Appellant's comments on the modified Draft Decision.

56. In light of the above, the Board of Appeal finds that the Agency did not breach Articles 50(1) and 51(5) and, on the basis of the content of the modified Draft Decision and the Contested Decision, carried out its assessment in a professional and scientific manner. The Board of Appeal therefore considers that the Appellant's first argument under this plea must be rejected.

57. Concerning the Appellant's second argument, namely that the Agency breached its legitimate expectations that its comments would be assessed in their entirety by the authorities in a professional and scientific way, the Board of Appeal has already explained in the above paragraphs that the Agency did not breach Articles 50(1) and 51(5) and followed correctly the procedure foreseen for the assessment of registrants' comments under dossier evaluation. In addition, the Agency has explained at the different steps of the decision-making process and in a professional and scientific manner its concerns and its reasons for not accepting the read-across proposal (see paragraphs 50 and 53 above). The Board of Appeal therefore finds that the Appellant's legitimate expectations were not disregarded as its arguments were considered in a scientific and professional way and this argument of the Appellant should be rejected. For the same reasons, the Appellant's argument that its right to be heard had been breached must be rejected.

58. With its third argument, the Appellant contends that, during the evaluation procedure, the Agency ignored the STOT data provided. The Appellant claims that information on

STOT was first introduced in its comments on the Draft Decision and was also present in the registration dossier for the read-across substance.

59. The Board of Appeal observes that this argument relates to the Agency's statement in the Contested Decision that *'it is not clear whether liver, kidney and spleen/blood cell toxicity occurs at the same dose levels with the same severity for both substances in repeated dose toxicity studies, thus allowing to conclude that the potency would be about the same related to systemic toxicity organ by organ'.*

60. The Board of Appeal further observes, as stated in paragraph 50 above, that this deficiency was already clearly identified in the same words by the Agency in the modified Draft Decision. This shortcoming had therefore been brought to the attention of the Appellant as a result of the Agency's examination of its comments on the Draft Decision and the first dossier update. Therefore, the Board of Appeal notes that the Agency considered that the information provided by the Appellant during the decision-making process did not address this deficiency. Consequently, the Agency did not amend the relevant part of the Draft Decision or modified Draft Decision. The Agency's assessment of the Appellant's dossier for the PNDT endpoint after the first update therefore resulted in the same outcome. The Board of Appeal finds therefore that rather than contending that the Agency did not take its comments on STOT into account, the Appellant rather disagrees with the outcomes of the assessment of these arguments. The Board of Appeal observes that in the second dossier update the Appellant included some further information on STOT (see paragraph 10 above). However, the Board of Appeal has found in paragraph 56 above that the Agency did not breach Articles 50(1) and 51(5) and that the Agency was justified in introducing a cut-off date after which comments on draft decisions and dossier updates could no longer be taken into account. Therefore, the Agency did not breach Articles 50(1) and 51(5) in not considering additional STOT data submitted by the Appellant after 6 March 2014.

61. The Board of Appeal therefore finds that the Agency did not ignore the Appellant's comments on STOT and that rejects the Appellant's third argument.

62. As to the additional argument that the Agency could have found information on STOT in the read-across substance dossier, the Board of Appeal recalls that it is not the task of the Agency to develop, or improve, read-across adaptations on the registrants' behalf (see Case A-006-2012, *Momentive Specialty Chemicals,* Decision of the Board of Appeal of 13 February 2014, paragraph 60). This argument is therefore also rejected.

63. Concerning the Appellant's fourth argument that Articles 50(1) and 51(5) were breached by the Agency when it did not take into account the PfA, as stated in paragraph 53 above the PfA was considered by the MSC in the decision-making process. The fact that the MSC did not accept the PfA and maintained the requirement for a PNDT study in the Contested Decision does not mean that the PfA was not considered. This argument is therefore rejected.

64. The Board of Appeal also finds that, whilst the fact that the PfA was taken into account was not made explicit in the Contested Decision, it was known by the Appellant who attended the MSC meeting of 10 to 13 June 2014, as explained in the Agency's Defence and not contested by the Appellant. The public minutes of the MSC meeting, reflecting its conclusions, were made publicly available on the Agency's website. The Board of Appeal observes that these minutes state that *'[o]ne PfA did not agree with ECHA that the proposed adaptation of the information requirement by the Registrant*

through read-across is not acceptable for the pre-natal developmental toxicity study (PNDT; OECD 414). This PfA considers the read-across plausible and indicated that it should be conditionally accepted pending the outcome of the fertility study and thus the request for the PNDT study should be removed.' The Board of Appeal considers therefore that the Appellant was aware that the PfA was considered by the Agency. The Appellant's fourth argument must therefore be rejected in its entirety.

65. The Appellant's fifth argument concerns the Agency's practice of not taking into account a registrant's comments and dossier updates after referral of a draft decision to the MSCAs. Relying in particular on the decision of the Board of Appeal of 10 June 2015 in Case A-001-2014, *CINIC Chemicals Europe*, the Appellant claims that the Agency should have taken into account the new information that the Appellant submitted after the referral of the Draft Decision to the MSCAs and should have re-examined the Appellant's dossier in light of those comments and as a result of a change of factual circumstances.

66. The Agency points out that its practice of not taking into account dossier updates submitted after the notification of a decision to the MSCAs is justified inter alia by the need to send the same draft decision to MSCAs and registrants in order to ensure that they both comment on decisions having the same content (see paragraph 34 above). However, in the present case, the Board of Appeal notes that the Appellant was invited to comment on the Draft Decision and then on the PfAs whilst the MSCAs were invited to submit PfAs on the modified Draft Decision. The Appellant and the MSCAs were therefore not called on to comment on decisions having exactly the same content and at the same point in time. Contrary to the Agency's assertion, the Board of Appeal finds that in the present case, the Agency's practice is not justified by the necessity to provide comments on identical documents as this was not the case. It can however be justified by the need to provide guarantees for MSCAs and registrants that the information contained in the registration dossier under evaluation is stable when it has to be examined by the MSCAs.

67. The Board of Appeal has previously held, at paragraph 78 of its decision in *CINIC Chemicals Europe*, cited at paragraph 65 above, 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). In *CINIC Chemicals Europe* the Board of Appeal then proceeded to assess whether this balance was achieved and in particular 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. *CINIC Chemicals Europe* concerned the results of a study performed by another registrant which had come to the knowledge of the appellant after the date at which the Agency had referred a draft decision to the MSCAs but before the decision was adopted. The Board of Appeal observed, at paragraph 81 of its decision, that the information provided by the appellant in that case 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. The Board of Appeal found, at paragraph 84 of the decision, that the information in question therefore constituted substantial new information that could potentially have influenced the Contested Decision as regards the need to perform the vertebrate animal study and should therefore, in that particular case, have been considered by the Agency before finalising the decision.

68. The Board of Appeal considers that the difference between *CINIC Chemicals Europe* and the present appeal stems from the importance and availability of the information relied on by the Appellant. In *CINIC Chemicals Europe* the information at issue was, first, not known to the registrant at the time of referral of the draft decision to the MSCAs and, second, could have potentially influenced the decision. In other words the information was both new and substantial. In the present case the information referred to by the Appellant is not new. The Appellant highlighted this fact in its submissions when it argued that the information submitted as part of the second dossier update formed part of the original registration dossier and should therefore have been examined by the Agency at the outset of the compliance check procedure (see paragraph 31 above). The Board of Appeal has also already found, in paragraphs 52 to 54 above, that the data submitted by the Appellant in its second dossier update consists of updated justifications based on information already included in the first registration update and as such has already been considered by the Agency and found to not affect the Draft Decision. This information cannot therefore be considered to be substantial. In the present case the Board of Appeal finds that the information referred to by the Appellant is not therefore substantial or new. The *CINIC* case cannot therefore be applied by analogy to the present case and the Appellant's arguments in that regard should be rejected.

69. The Appellant's first plea is therefore rejected.

The second plea, alleging that the Contested Decision lacks a legal basis

Arguments of the Parties

70. By its second plea, the Appellant claims that the Contested Decision lacks a legal basis. In particular, the Appellant argues that its dossier included a valid read-across approach to fulfil the requirements of the PNDT endpoint. The Appellant explains that it submitted data justifying a read-across approach on the basis of studies following test methods OECD 414 and 415 on the read-across substance and a screening study following test method OECD 421 on the Substance. The Appellant submits that the properties of the read-across substance and the Substance '*are likely to be similar or […] follow a regular pattern and that this similarity is a result of the structural similarity'.* The Appellant concludes that as the PNDT endpoint is covered in its registration dossier, the Agency has '*illegally based the Contested Decision on Article 41'.*

71. The Agency refutes the Appellant's second plea and stresses that, while the Agency has a duty to accept read-across proposals when the conditions of Section 1.5 of Annex XI are met, the Appellant's registration dossier, as it stood on 6 March 2014, did not meet the conditions of this Annex. The Agency concludes that the Appellant's claim that the Contested Decision lacks a legal basis is unfounded.

Findings of the Board of Appeal

72. The Board of Appeal notes that the Contested Decision is a decision following a compliance check initiated pursuant to Article 41 and adopted pursuant to Article 51. Consequently a legal basis exists for it. However, the Board of Appeal observes that under this plea, the Appellant argues in essence that its registration dossier satisfied the information requirements for the PNDT endpoint through a valid read-across

approach and that in requesting a PNDT study the Agency has not assessed its registration dossier correctly.

73. The Board of Appeal therefore finds that, rather than contending that the Contested Decision lacks a legal basis, the arguments raised by the Appellant concern the assessment performed by the Agency of the Appellant's registration dossier. The Board of Appeal will therefore assess whether the Agency made an error of assessment.

74. When assessing whether the Agency has made an error of assessment, the Board of Appeal must examine whether the Agency has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached (see, by analogy, Case T-71/10, *Xeda International and Pace International v Commission*, EU:T:2012:18, paragraph 71; see also Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 42).

75. The Board of Appeal observes that in the present case the Appellant's submissions were aimed at fulfilling the PNDT endpoint through a read-across adaptation. The Agency's assessment, disputed by the Appellant, therefore relates to the validity of the read-across proposal.

76. The Board of Appeal observes that in the context of the assessment of read-across proposals under the REACH Regulation the Agency's role is to verify whether a registrant's read-across adaptation satisfies the requirements of Section 1.5 of Annex XI. The Board of Appeal considers that Article 13 TFEU and Article 25(1) of the REACH Regulation do not impose any additional duties on the Agency in this respect. If a registrant's proposed use of read-across does not comply with the requirements of Section 1.5 of Annex XI the Agency is entitled to reject the proposal (see Case A-006-2012, *Momentive Specialty Chemicals*, Decision of the Board of Appeal of 16 January 2013, paragraph 98, and Case A-001-2012, *Dow Benelux*, Decision of the Board of Appeal of 19 September 2013, paragraph 116).

77. The Board of Appeal notes that the Agency has, in all of the different iterations of the Draft Decision, consistently informed the Appellant of the reasons why the read-across proposal did not fulfil the requirements of Section 1.5 of Annex XI.

78. The Board of Appeal has already found that the Agency carried out a professional and scientific assessment of the arguments put forward by the Appellant (see paragraph 56 above). The Board of Appeal notes that there is a difference of opinion between the Appellant and the Agency on the interpretation of the data and arguments provided regarding the read-across proposal. If the Agency considers that the conditions in Section 1.5 of Annex XI have not been met then it must require the registrant to provide the information necessary to satisfy the endpoint in question (see above in paragraph 76). In light of the above, the Board of Appeal concludes that the Agency has carefully taken all the relevant elements into account and has not made an error of assessment.

79. The Appellant's argument and second plea as to the lack of legal basis of the Contested Decision must therefore be rejected.

The third plea, alleging a breach of the principle of proportionality

Arguments of the Parties

80. The Appellant argues that the Contested Decision breaches the principle of proportionality as it imposes substantial testing burdens on the Appellant without a sufficient likelihood that they will provide meaningful results. The Appellant submits that in its comments on the Draft Decision it questioned the scientific merits of a PNDT study to cover the PNDT endpoint. The Appellant reproduces for the purpose of the present appeal a section of its comments on the Draft Decision concerning a one-generation reproduction toxicity study following test method OECD 415 performed on the read-across substance and concluding that the read-across substance is not teratogenic. These comments on the Draft Decision also refer to the results of the screening study on the Substance, which the Appellant concludes demonstrates that the Substance is not a reproductive toxicant. The Appellant then combines the results of these two studies with three other studies to conclude that it is not justified to conduct further animal studies. The Appellant concludes that the Contested Decision is illegal in requesting the study to be conducted as it violates the principle of proportionality.

81. The Appellant also submits that the Agency by rejecting the read-across proposal and requesting the PNDT study to be conducted violated the principle of proportionality as less onerous measures were available to satisfy the information request.

82. The Agency argues that since the read-across proposal made by the Appellant did not fulfil the requirements of the REACH Regulation the request for the PNDT study cannot be disproportionate without arguing that the REACH Regulation itself is disproportionate in this regard. The Agency adds that the Board of Appeal has no competence to assess the legality of the REACH Regulation and has previously refused to do so.

Findings of the Board of Appeal

83. As regards the Appellant's third plea, alleging that the Agency breached the principle of proportionality by imposing substantial testing burdens on the Appellant without a sufficient likelihood of meaningful results, the Board of Appeal recalls that a PNDT study constitutes standard information which must be provided pursuant to Section 8.7.2 of Annex IX. The Board of Appeal further recalls its findings, at paragraph 56 above, that the Agency was justified in rejecting the read-across proposed by the Appellant. Once the Agency had rejected the proposed read-across, it enjoyed no margin of discretion regarding the request for a PNDT study (see paragraph 78 above). Consequently, it did not breach the principle of proportionality by requesting the studies to be performed (see, by analogy, Case T-637/11, *Euris Consult v Parliament*, EU:T:2014:237, paragraph 101).

84. The Board of Appeal finds therefore that the Contested Decision was not disproportionate and that the Appellant's plea in this regard must be rejected.

The fourth plea, alleging a breach of animal welfare requirements

Arguments of the Parties

85. The Appellant argues that the Contested Decision breaches the principle of animal welfare as set out in Articles 25(1) and 13(1) as well as recital 47, as the PNDT study is not required by law and the study will likely not provide scientifically meaningful results. The Appellant further submits that conducting the PNDT study would lead to

the needless suffering of the animals involved, which would violate the overarching animal welfare principles of the REACH Regulation as well as Directive No 2010/63/EC of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

86. The Agency argues that the Board of Appeal has held, in paragraphs 96 to 99 of its decision of 13 February 2014 in Case A-006-2012, *Momentive Specialty Chemicals*, that the Agency is entitled to reject an adaptation proposal if it does not comply with the specific or general adaptation rules of the REACH Regulation. The Agency adds that the registrant's duty to comply with Article 25 includes not only identifying the possibility to use an adaptation but also providing sufficient justification in order to meet the respective requirements for that adaptation. The Agency argues further that the same reasoning applies with regard to Directive No 2010/63/EC for the respect of the principles of replacement, reduction and refinement of animal testing also reflected in the REACH Regulation. The Agency adds that the Appellant has in the present case not fulfilled the PNDT information requirement by the time of the referral of the Draft Decision to the MSCAs and that the Contested Decision was therefore correct in requiring the Appellant to conduct a PNDT study. The Agency therefore did not violate Articles 13(1), 25 or recital 47.

Findings of the Board of Appeal

87. The Board of Appeal notes that Article 25(1) provides that '*[i]n order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.*'

88. The Board of Appeal has already found that the Agency was justified in rejecting the Appellant's read-across proposal by the Appellant on the grounds that the conditions of Section 1.5 of Annex XI were not met.

89. Consequently, the Agency had no discretion as to whether to request the Appellant to perform the PNDT study, which is a standard information requirement under Section 8.7.2 of Annex IX (see paragraph 78 above). Accordingly, contrary to the Appellant's claims under its fourth plea, the Agency did not breach the animal welfare requirements in Articles 13(1), 25(1) and recital 47 by requesting a PNDT study. The Board of Appeal therefore rejects the Appellant's fourth plea.

Refund of the appeal fee

90. 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 decision is rectified in accordance with Article 93(1) or the appeal is decided in favour of an appellant.

91. As the appeal has been dismissed the appeal fee shall not be refunded.

Effects of the Contested Decision

92. According to Article 91(2), an appeal before the Board of Appeal shall have suspensive effect.

93. The part of the Contested Decision challenged in the present proceedings, and upheld by the Board of Appeal, required the Appellant to submit the required information by 28 September 2015, which is 12 months and 7 days from the date of adoption of the Contested Decision. The Board of Appeal considers that, because of the duration of the present appeal proceedings, the deadline set in the Contested Decision should be interpreted, in light of the principle of suspensive effect laid down in Article 91(2), as if it referred to 12 months and 7 days from the date of notification of the final decision of the Board of Appeal.

94. Consequently, the Appellant shall submit the information required in the Contested Decision within 12 months and 7 days from the date of notification of the Board of Appeal's Decision in the present case.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal;**
2. **Decides that the information required by the Contested Decision shall be submitted by 13 October 2017;**
3. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal