

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

**30 January 2018**

*(Testing proposal – Read-across – Duty to state reasons – Article 25 –  
Legitimate expectations)*

|                             |  |
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| <b>Case number</b>          | A-005-2016   |
| <b>Language of the case</b> | English  |
| <b>Appellant</b>            | Cheminova A/S, Denmark   |
| <b>Representatives</b>      | Ruxandra Cana and Indiana de Seze<br>Steptoe & Johnson LLP, Belgium  |
| <b>Intervener</b>           | PETA International Science Consortium Ltd (PISC), United Kingdom   |
| <b>Contested Decision</b>   | TPE-D-2114328778-35-01/F of 26 April 2016 adopted by the European Chemicals Agency (the '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) (the 'REACH Regulation') |

**THE BOARD OF APPEAL**

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

Registrar: Alen Močilnikar

gives the following

## Decision

### Background to the dispute

1. In 2013, the Appellant submitted registration dossiers for both sodium O,O-diethyl dithiophosphate (EC No 222-079-2; CAS No 3338-24-7) (the 'Substance'), and sodium O,O-diisobutyl dithiophosphate (EC No 258-508-5; CAS No 53378-51-1) (the 'source substance'). The Appellant is the lead registrant for both the Substance and the source substance. The present appeal proceedings concern the Agency's testing proposal decision concerning the Substance (the 'Contested Decision').
2. The Appellant's registration dossier for the Substance initially included the following statement for both '*repeated dose toxicity: oral. 90 [days]*' and '*developmental toxicity/teratogenicity*' corresponding to Sections 8.6.2 and 8.7.2 of Annex IX to the REACH Regulation (all references to Articles, Recitals and Annexes hereinafter concern the REACH Regulation unless stated otherwise):  
*'[...] Data waiving-other justification. The information requirements for this study will be covered by read across from [the source substance]. The study for [the source substance] is not yet available but has been proposed and is currently being evaluated by [the Agency]. An update of the dossier, including this read across, will follow.'*
3. The Appellant's registration dossier for the source substance contained the following testing proposals:  
*'90-day oral toxicity study (OECD [test guideline] 408) in rodents, oral route using the [source substance];*  
*Developmental toxicity/teratogenicity study (OECD [test guideline] 414) in rats, oral route using the [source] substance [...].'*
4. Between 29 April and 13 June 2014, pursuant to Article 40(2), the Agency conducted a public consultation for the testing proposals on the source substance. No information was received from third parties as a result of the consultation.
5. On 30 April 2014, the Agency sent a letter concerning the Substance to the Appellant informing it that the Agency '*considers adaptations to results of tests to be performed on [the source substance] as testing proposals on that [source] substance that are to be assessed by the Agency under Article 40*'. The letter further invited the Appellant '*to remove the waiver and to identify the testing proposals within IUCLID in the endpoint study record by selecting "experimental study planned" in the field "study result type" [...]. [The Agency] will then examine the testing proposals in accordance with the procedure set out in Articles 40, 50 and 51 [...].*' The letter concluded that '*if no update is made within this period [the Agency] will treat your adaptations as testing proposals on the [source] substance and examine the testing proposal in accordance with the process set out in Articles 40, 50 and 51 [...]. [The Agency] will then examine your justification to test the [source] substance according to the general rules for adaptation set in Annex XI, Section 1.5. [...].*'
6. On 4 June 2014, the Appellant updated its registration dossier for the Substance to state that it proposed to perform a 90-day oral toxicity study (OECD TG 408) and a developmental toxicity/teratogenicity study (OECD TG 414) on the source substance. The update included a justification for a read-across approach, from the source substance to the Substance, for the endpoints concerned. The dossier update also stated that the registration dossier for the Substance would be further updated to substantiate the read-across from the results of tests on the source substance.

7. Between 18 September and 3 November 2014, pursuant to Article 40(2), the Agency conducted a third party consultation for the Substance on testing proposals concerning '*reproductive toxicity (pre-natal developmental toxicity)*' and '*sub-chronic toxicity (90-day): oral*'. The third party consultation on the testing proposals for the Substance published on the Agency's website included a comment that the proposed testing was on the source substance. No information was received from third parties as a result of the consultation.
8. On 30 January 2015, the Agency adopted a decision on the testing proposals for the source substance. According to the decision, the Appellant was required to provide the following information on the source substance by 6 February 2017:
  - Sub-chronic toxicity study (90-day), oral route (Section 8.6.2. of Annex IX; test method: EU B.26/OECD TG 408) in rats; and
  - Pre-natal developmental toxicity study (Section 8.7.2. of Annex IX; test method: EU B.31/OECD TG 414) in rats or rabbits, oral route.
9. On 30 March 2015, the Agency sent to the Appellant a draft decision concerning the testing proposals on the Substance and invited it to provide comments within 30 days. In the draft decision, the Appellant was requested to update its dossier with the following information on the Substance:
  - Sub-chronic toxicity study (90-day), oral route (Section 8.6.2. of Annex IX; test method: EU B.26/OECD TG 408) in rats; and
  - Pre-natal developmental toxicity study (Section 8.7.2. of Annex IX; test method: EU B.31/OECD TG 414) in rats or rabbits, oral route.
10. The draft decision concerning the Substance also stated that '*the originally proposed tests for a 90-day oral toxicity study (OECD 408) and developmental toxicity/teratogenicity study (OECD 414) proposed to be carried out using [the source] substance [...] are rejected pursuant to Article 40(3)(d)*'.
11. On 14 April 2015, the Agency received comments from the Appellant on the draft decision concerning the Substance. The Appellant stated that no further animal testing was required to satisfy the two endpoints. It would satisfy the two endpoints by providing in a dossier update a weight-of-evidence approach, as well as information from quantitative structure–activity relationship models ('QSAR') derived from the OECD QSAR toolbox, exposure scenarios and the composition of the Substance to justify the read-across from the source substance to the Substance. The Appellant requested a 6-week extension to prepare a dossier update.
12. On 7 May 2015, the Appellant submitted '*a dossier update including justifications in lieu of testing proposals for an OECD [TG] 408 and an OECD [TG] 414 study on the [Substance]*'.
13. On 21 May 2015, a telephone conference took place between the Agency and the Appellant to discuss the registration for the Substance and the proposed read-across from the source substance to the Substance. According to the Agency's minutes of that meeting, the Agency agreed to extend the time given for the Appellant to update its registration dossier until 6 August 2015 for the Appellant to improve its read-across adaptation.
14. On 4 June 2015, the Appellant further updated its registration dossier for the Substance with an amended justification for the read-across adaptation. This justification proposed performing tests on the source substance and to read-across the results to the Substance. According to the Contested Decision the '*ECHA Secretariat considered the Registrant's comments and update. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made*'.

15. On 3 March 2016, the Agency notified a revised draft decision on the testing proposals for the Substance to the Member State Competent Authorities ('MSCAs') and invited them, pursuant to Article 51(1), to submit proposals for amendment to the draft decision within 30 days. No proposals for amendment were submitted by the MSCAs.
16. Pursuant to Article 51(3), the Agency adopted the Contested Decision on the testing proposals for the Substance.
17. According to the Contested Decision, which was taken under Article 40(1):  
*'[The Agency] has examined the following testing proposals submitted as part of the [Appellant's] registration dossier [...] for sodium O,O-diethyl dithiophosphate (EC No 222-079-2 (CAS No 3338-24-7), [the 'Substance']), submitted by [the Appellant]:*
  - *90-day oral toxicity study (OECD [TG] 408) in rodents, oral route using the [source substance];*
  - *Developmental toxicity/teratogenicity study (OECD [TG] 414) in rats, oral route using the [source] substance [...].'*
18. The Contested Decision requires the Appellant to provide the following information on the Substance by 3 May 2018:
  - Sub-chronic toxicity study (90-day), oral route (Section 8.6.2. of Annex IX; test method: EU B.26/OECD TG 408) in rats; and
  - Pre-natal developmental toxicity study (Section 8.7.2. of Annex IX; test method: EU B.31/OECD TG 414) in rats or rabbits, oral route.
19. The Contested Decision also states that *'the originally proposed tests for a 90-day oral toxicity study (OECD [TG] 408) and developmental toxicity/teratogenicity study (OECD [TG] 414) proposed to be carried out using the [source] substance [...] are rejected pursuant to Article 40(3)(d).'*

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

20. On 25 July 2016, the Appellant filed this appeal.
21. On 15 September 2016, the Chairman of the Board of Appeal adopted a decision on the Appellant's confidentiality requests. The Chairman accepted the Appellant's request for confidential treatment with respect to the registration number of the addressee of the Contested Decision, the personal data of the staff of the Appellant and the registration tonnage band. The Chairman however rejected the Appellant's request for confidential treatment with respect to the identity of the Appellant.
22. On 28 September 2016, the Agency filed its Defence.
23. On 12 December 2016, the Appellant filed its observations on the Defence.
24. On 18 January 2017, PISC was granted leave to intervene in support of the Appellant.
25. On 13 February 2017, the Agency filed its observations on the Appellant's observations on the Defence.
26. On 20 March 2017, the Intervener filed its statement in intervention.
27. On 18 April 2017, the Agency filed its observations on the statement in intervention. The Appellant informed the Board of Appeal that it had no comments on the statement in intervention.
28. On 28 June 2017, a hearing was held at the Appellant's request. At the hearing, the Parties and the Intervener made oral submissions and responded to questions from the Board of Appeal.

**Form of order sought**

29. The Appellant, supported by the Intervener, requests the Board of Appeal to annul the Contested Decision in its entirety, order the refund of the appeal fee and take such other or further measures as justice may require.
30. If the appeal is found to be inadmissible or is dismissed the Appellant requests the Board of Appeal to amend the deadline set in the Contested Decision to take account of the suspensive effect of the appeal.
31. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

**Reasons**

32. The Appellant raises the following pleas in law in support of its appeal:
  - A. The Agency exceeded its powers by adopting the Contested Decision on the wrong legal basis;
  - B. Breach of Article 40(2) regarding the third party consultation;
  - C. Breach of Sections 1.2., 1.3. and 1.5. of Annex XI regarding adaptations to standard testing requirements;
  - D. Breach of the principle of legal certainty;
  - E. Failure to take into account all available information;
  - F. Breach of the duty to state reasons;
  - G. Breach of the duty of good administration;
  - H. Breach of Article 25 and the principle of proportionality; and
  - I. Breach of the principle of legitimate expectations.

**A. The Agency exceeded its powers by adopting the Contested Decision on the wrong legal basis****Arguments of the Parties**

33. The Appellant, supported by the Intervener, argues that the Agency committed a procedural error by adopting the Contested Decision on the basis of Article 40. In support of its plea the Appellant argues amongst other things that:
  - its registration dossier for the Substance did not contain testing proposals for the two endpoints addressed in the Contested Decision,
  - its registration dossier for the Substance *'referred to planned testing on the [source] substance in the context of justifications supporting the fact that testing on the Substance was not needed, in full compliance with Annex XI'*,
  - the use of Article 41, instead of Article 40, as the legal basis for the decision would have allowed it to become aware of the Agency's reasons for rejecting the adaptation in the Substance registration dossier at an earlier stage. The Appellant would then have had a better opportunity to address these reasons, and
  - the compliance check procedure (under Article 41) is more flexible as, unlike the testing proposal procedure (under Article 40), it does not need to be concluded within a certain time-limit. Following the compliance check procedure would therefore have allowed the Agency to examine the registration dossier for the Substance after the relevant sections had been updated with the results of the testing on the source substance.

34. The Appellant also argues that the Agency exceeded its power by assessing the Appellant's proposed read-across adaptation under Article 40 rather than Article 41. Adaptations of standard information requirements pursuant to Annex XI can only be evaluated under Article 41. The Agency should not therefore have evaluated its read-across proposals under Article 40 and was incorrect in concluding that the requirements of Section 1.5. of Annex XI had not been met.
35. The Agency disputes the Appellant's arguments for the following reasons:
- at the start of the examination of the dossier for the Substance, the updated registration dossier included testing proposals. Proposals for tests to be performed on substances other than the registered substance subject to evaluation must be examined under Article 40. This was made clear in the Agency's letter of 30 April 2014,
  - Article 40(1) '*sets no restrictions with regard to testing "on the registered substance"*'. It explicitly refers to '*any*' testing proposal, as long as it is aimed at providing the information specified in Annexes IX and X,
  - the REACH Regulation sets clear deadlines for the Agency to decide on testing proposals. There is no legal basis in the REACH Regulation for the Agency to await the outcome of testing on a source substance, and
  - registration dossiers must contain, for each endpoint, data on experimental studies, adaptations, or testing proposals.

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

36. The Contested Decision is entitled '*Decision on testing proposal(s) set out in a registration pursuant to Article 40(3) [...]'*.
37. According to the Contested Decision on the Substance, '*the originally proposed tests for a 90-day oral toxicity study (OECD [TG] 408) and developmental toxicity/teratogenicity study (OECD [TG] 414) proposed to be carried out using the [source] substance [...] are rejected pursuant to Article 40(3)(d) [...]'*.
38. The Appellant argues, in essence, that its registration dossier did not contain a testing proposal but rather an adaptation pursuant to Annex XI which should have been examined in accordance with the compliance check procedure under Article 41. According to Article 41(1)(b):
- '1. The Agency may examine any registration in order to verify any of the following:*
- [...]*
- (b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI'*.
39. The Appellant's registration dossier for the Substance submitted in 2013 contained the following statement concerning Sections 8.6.2. and 8.7.2. of Annex IX:
- 'Data waiving-other justification. The information requirements for this study will be covered by read across from [the source substance]. The study for this [the source substance] is not yet available but has been proposed and is currently being evaluated by [the Agency]. An update of the dossier including this read across, will follow'*.
40. In its letter of 30 April 2014 (see paragraph 5 above) the Agency stated, amongst other things, that:

*'[i]f no update is made [...] [the Agency] will treat your adaptations as testing proposals on the [source] substance and examine the testing proposal in accordance with the process set out in Articles 40, 50 and 51 [...]. [The Agency] will then examine your justification to test the [source] substance according to the general rules for adaptation set in Annex XI, Section 1.5'.*

41. The Appellant subsequently updated its registration dossier for the Substance several times. The Appellant emphasised that it intended to satisfy the registration requirements in Sections 8.6.2. and 8.7.2. of Annex IX by using a read-across adaptation, applying the results from testing on the source substance to the Substance.
42. Registration dossier updates for the Substance included:
  - on 4 June 2014, the Appellant updated its dossier to clarify that it intended to fill the two information requirements for the Substance by means of a read-across adaptation. The Appellant also included additional justifications to support its read-across proposal,
  - on 7 May 2015, the Appellant updated its dossier to include a reference to future results of on-going studies on the source substance. These studies, concerning Sections 8.6.2 and 8.7.2 of Annex IX, were required as a result of the Agency's testing proposal decision of 30 January 2015 (see paragraph 8 above) on the source substance, and
  - on 4 June 2015, the Appellant updated its dossier with further justifications for its proposed read-across adaptation.
43. In other exchanges with the Agency, for example in its comments on the draft decision of 14 April 2015, the Appellant made it clear that it intended to meet the registration requirements in Sections 8.6.2. and 8.7.2. of Annex IX by using a read-across adaptation. During the telephone conference of 21 May 2015 with the Agency the Appellant explained that it intended to improve its read-across justification to satisfy those two endpoints. The Agency granted the Appellant additional time to submit a registration dossier update improving the justification for the read-across adaptation (see paragraph 13 above).
44. It is therefore clear from the Appellant's registration dossier, as updated on several occasions, and from other communications with the Agency, that the Appellant had no intention of performing tests on the Substance in order to comply with the registration requirements in Sections 8.6.2. and 8.7.2. of Annex IX. It is also clear that the Appellant at no point intended to submit testing proposals on the Substance for those two endpoints. The Appellant intended to satisfy the two endpoints concerned by use of a read-across adaptation using results on the source substance to read across to the Substance.
45. The Appellant's read-across adaptation should therefore have been assessed by way of a compliance check under Article 41(1)(b). The Contested Decision, which was adopted on the basis of Article 40(3), was therefore adopted on the wrong legal basis.
46. However, the procedures for adopting decisions under Articles 40 and 41 are similar. In particular, both Articles 40(3) and 41(3) remit to the decision-making procedures in Articles 50 and 51.
47. One difference between the two procedures is the requirement in Article 40(2) for a public consultation to be conducted on testing proposals. However, such a third party consultation is not detrimental to the interests of a registrant. On the contrary, the third party consultation could be beneficial to the registrant's interest if information derived from the consultation means that the proposed testing does not need to be conducted as the endpoint in question can be satisfied in other ways. A third party consultation is not detrimental to the interests of a registrant even if no relevant information is forthcoming.

48. The Appellant argues that another difference between the two procedures is that under Article 41 the Agency may have had more flexibility as to the timing of its decision-making. Under Article 40, time restrictions are imposed for the examination of testing proposals. According to Article 43(2)(b), '*[i]n the case of phase-in substances, the Agency shall prepare the draft decisions in accordance with Article 40(3) [...] by 1 June 2016 for all registrations received by 1 June 2013 containing proposals for testing in order to fulfil the information requirements in Annex IX only.*' The Appellant argues that if the decision was taken under Article 41 the Agency could have waited for the results of the testing on the source substance before evaluating the read-across adaptation for the Substance.
49. However, the Appellant would not be entitled to additional time under Article 41 to develop its read-across adaptation. The Agency did not have a legal obligation, under either Article 40 or Article 41, to wait for the Appellant to improve the justification for its read-across adaptation. It should also be noted that, under the testing proposal decision-making procedure followed by the Agency in the present case, additional time was granted to the Appellant to improve its justification (see paragraph 13 above).
50. In addition, the Agency made a detailed assessment of the Appellant's proposed read-across adaptation as summarised in the Contested Decision (Section III, '*Statement of reasons*').
51. The Agency's rejection of the read-across adaptation is set out in a way which allows the Appellant to understand why it was not accepted by the Agency. The Agency would have been required to examine the proposed read-across adaptation against the same criteria and justify its conclusions in a decision in the same way under the compliance check procedure.
52. The Appellant also alleges that the Agency exceeded its powers by assessing its proposed read-across adaptation under Article 40 rather than Article 41 (see paragraph 34 above).
53. It is correct that under Article 41(1)(b) (cited in paragraph 38 above) the Agency may examine Annex XI adaptations, including read-across proposals, contained in registration dossiers. However, Article 40(3)(c) also allows the Agency to evaluate Annex XI adaptations under the testing proposal procedure. According to this provision:  
*'[...] [t]he Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 50 and 51:*  
*[...]*  
*(c) a decision in accordance with points (a), (b) or (d) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI [emphasis added].*
54. Furthermore, read-across adaptations are assessed against the criteria set out in Annex XI regardless of whether the assessment is conducted pursuant to the compliance check procedure (Article 41) or the testing proposal procedure (Article 40).
55. The Agency did not therefore exceed its powers by assessing the Appellant's read-across adaptation under Article 40 rather than Article 41.
56. The Appellant's argument that if the Agency had adopted the Contested Decision under Article 41 it would have been in a better position to address the Agency's rejection of its read-across adaptation is also rejected. The Agency's examination and reasons for the rejection of the read-across adaptation were included in the draft decision of 30 March 2015. The Appellant therefore had the opportunity to provide comments on the Agency's reasons for rejecting the read-across adaptation in its comments on the draft decision. This opportunity to comment would have been the same if the draft decision had been taken under Article 40 or 41.

57. Throughout the decision-making procedure, and on several occasions, the Agency made it known to the Appellant that the proposed read-across adaptation was deficient and the reasons for this deficiency were explained. For example, this was made clear to the Appellant in the Agency's letter of 30 April 2014 (see paragraph 5 above) and in the draft decision of 30 March 2015. Although the Appellant updated its registration dossier, the deficiency identified by the Agency was not remedied by the Appellant. The fundamental reason for the Agency rejecting the proposed read-across adaptation, the fact that the Appellant had not demonstrated that the *'toxicological [...] properties [of the Substance and the source substance] are likely to be similar or follow a regular pattern'*, did not therefore change during the decision-making process.
58. In conclusion, in light of paragraphs 46 to 57 above, the reliance on Article 40 rather than Article 41 as the legal basis for the Contested Decision does not lead to a different assessment of the Appellant's registration dossier for the endpoints in question and would not therefore have led to a different decision. Furthermore, the Agency's error in choice of legal basis did not deprive the Appellant of the procedural guarantees set out in the relevant provisions of the REACH Regulation, in particular Articles 50 and 51 thereof. The Appellant has not established the existence of any of the adverse consequences alleged by them (see, by analogy, judgment of 19 March 2003, *CMA CGM and Others v Commission*, T-213/00, EU:T:2003:76, paragraphs 101 to 103).
59. In view of the above, the Appellant's plea that the Contested Decision should be annulled on the grounds that it was adopted on the wrong legal basis is rejected.

## **B. Breach of Article 40(2) regarding the third party consultation**

### **Arguments of the Parties**

60. The Appellant argues that *'the third party consultation [organised] for the [Substance] did not refer to testing on the Substance itself, it only referred to testing on the [source] Substance. Third parties, therefore, had no information that the Agency would consider requesting testing on the Substance itself. Had that been the case, it cannot be excluded that third parties would have brought additional information, which might have changed the final decision. As things stood, it can be expected that third parties would not have seen the need to comment on proposed testing on the [source] substance since these tests had already made the object of a separate third party consultation.'*
61. The Agency argues that the third party consultation was conducted in a transparent way and indicated the testing proposal made by the Appellant.

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

62. The Appellant's arguments related to the third party consultation in effect allege a breach of Article 40(2).
63. The first sentence of Article 40(2) states that *'[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 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...'*
64. The testing proposal for the Substance, as published on the Agency's website on 18 September 2014, included the following information:

|   |  |
|---|--|
| 'Name   | <i>sodium O,O-diethyl dithiophosphate [the Substance]    Note: testing proposed with sodium O,O-diisobutyl dithiophosphate (EC 258-508-5) [the source substance]</i> |
| EC Number   | 222-079-2  |
| CAS Number  | 3338-24-7  |
| Hazard endpoint for which vertebrate testing was proposed | Reproductive toxicity (pre-natal developmental toxicity)   |
| Date of publication to call for available information     | 18/09/2014   |
| Deadline for submitting information                       | 03/11/2014   |
| Hazard endpoint for which vertebrate testing was proposed | Sub-chronic toxicity (90-day): oral  |
| Date of publication to call for available information     | 18/09/2014   |
| Deadline for submitting information                       | 03/11/2014'.   |

65. The testing proposal for the Substance, as published on the Agency's website on 18 September 2014, therefore included all the information required by Article 40(2).
66. The testing proposal consultation also included the statement next to the name of the Substance, '*Note: testing proposed with [the source substance]*'. This additional information is not a requirement of Article 40(2). However, the Appellant has not demonstrated why the provision of this additional information would prevent third parties from providing relevant information on the Substance, as alleged by the Appellant. On the contrary, it might have encouraged the submission of information on the source substance as well as on the Substance if such information was available.
67. The testing proposal published on the Agency's website did not therefore infringe Article 40(2). The Appellant's plea that the third party consultation for the Substance breached Article 40(2) is therefore rejected.

**C. Breach of Sections 1.2., 1.3. and 1.5. of Annex XI regarding adaptations to standard testing requirements**

**Arguments of the Parties**

68. The Appellant argues that the proposed adaptations for the endpoints concerned comply with the requirements of Annex XI, and in particular Sections 1.2., 1.3. and 1.5. thereof. By concluding that the adaptations do not meet these requirements the Contested Decision infringes Annex XI. In support of its plea the Appellant argues that:
- the results of the testing on the source substance would strengthen the read-across hypothesis and allow a conclusion to be drawn on the toxicological profile of the Substance without having to perform testing on the Substance itself. However, the testing on the source substance was not available because the rules of the REACH Regulation do not allow such testing to proceed without the Agency first conducting a testing proposal examination,
  - the Agency's approach makes it impossible for a registrant to apply a grouping or read-across approach to Annex IX and X endpoints where the source and target substances have been registered at the same time,

- Annex XI must be read in the context of the principles of the REACH Regulation and the overriding principles of EU law, including animal welfare. In light of these principles the Agency should be able to accept a legitimate delay in the availability of the studies on the source substance before deciding to request testing on the Substance,
  - the read-across is supported by a QSAR model, and
  - in its dossier update of 4 June 2015, the Appellant proposed to strengthen its read-across adaptation by performing an OECD TG 422 study on the Substance. In its registration dossier for the Substance the Appellant used the results of an OECD TG 422 study on the source substance to satisfy the information requirement in Section 8.7.1. of Annex VIII (screening for reproductive/developmental toxicity). The Agency should have adopted a *'tiered approach'* and allowed the Appellant a longer time to comply with the Contested Decision. This would have allowed it to perform an OECD TG 422 study on the Substance to strengthen the read-across justification and only then, if necessary, perform the OECD TG 408 and OECD TG 414 studies on the Substance requested in the Contested Decision.
69. The Agency stated during the appeal proceedings that the structural similarity of the Substance and the source substance has been established. However, Section 1.5. of Annex IX also requires that *'the properties of source and target substances are likely to be similar as a result of this structural similarity and that properties of the target substance can be predicted from data on the source substance'*.
70. The Agency argues that, in the absence of data for either the Substance or the source substance for the two endpoints, it remains speculative whether the read-across adaptation proposed will be shown to be valid.
71. The Agency further argues that the absence of information on the systemic toxicity of the Substance after repeated administration means that it is not possible to establish that the two substances, although structurally similar, are likely to have similar properties, as required by Section 1.5. of Annex XI.
72. The Agency argues, moreover, that, in offering to perform an OECD TG 422 study on the Substance, the Appellant acknowledged that the proposed read-across adaptation lacks information demonstrating the similarity between the properties of the two substances. Until the OECD TG 422 study on the Substance has been completed it is not known whether the results will support the Appellant's read-across adaptation.
73. The Agency also argues that a comparison of structural similarities and endpoint-specific properties established using the OECD QSAR 'toolbox' model predicts that the properties of the Substance and the source substance are similar. Whilst the Agency recognises that this constitutes valid supporting information on similarities in toxicological profiles, it does not establish that the properties of the two substances are similar for complex higher tier endpoints such as repeated-dose toxicity and pre-natal developmental toxicity.
74. In addition, the Agency argues that *'if there had been a reliable basis to predict properties between the [Substance] and the [source] substance, [the Agency] would have approved the proposed testing as plausible. However, in the case at hand, the conditions of Annex XI, 1.5. were not met and therefore, the suggested adaptation could not be considered plausible'*.
75. The Intervener argues that the Appellant has shown a likelihood of toxicological similarity between the two substances. A lack of data on the toxicological properties of the source substance does not mean that the Substance and the source substance cannot have similar properties.

76. The Intervener further argues that the Agency did not explain why conducting an OECD TG 422 study on the Substance only, which would have minimised animal testing, would not be sufficient to address the alleged flaws in the proposed read-across adaptation.

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

77. Article 13(1) provides that information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. The Appellant argues that, contrary to the findings of the Contested Decision, the adaptations proposed for the two endpoints in question meet the requirements of Sections 1.2., 1.3. and 1.5. of Annex XI. The Board of Appeal will address the Appellant's arguments in relation to each of these provisions in turn.

#### **1. Breach of Section 1.2. of Annex XI – Weight of Evidence**

78. Under Section 1.2. of Annex XI:

*'There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.*

*[...]*

*Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:*

*- further testing on vertebrate animals for that property shall be omitted,*

*[...].'*

79. At the hearing the Appellant clarified that the adaptations proposed were not a weight of evidence adaptation within the meaning of Section 1.2. of Annex XI.
80. The Appellant's plea that the Agency breached Section 1.2. of Annex XI is therefore rejected.

#### **2. Breach of Section 1.3. of Annex XI - QSAR**

81. Under Section 1.3. of Annex XI, results obtained from valid QSARs may indicate the presence or absence of a property. Subject to certain conditions set out in this provision, the results of QSARs may be used to satisfy specific registration requirements.
82. At the hearing the Appellant confirmed that the evidence submitted from the use of the OECD QSAR toolbox model, included in the registration update of 7 May 2015, was used to support the proposed read-across adaptation pursuant to Section 1.5. of Annex XI. The evidence was not used to support a QSAR adaptation pursuant to Section 1.3. of Annex XI. The registration dossier for the endpoints in question did not therefore include a QSAR adaptation within the meaning of Section 1.3. of Annex XI.
83. The Appellant's plea that the Agency breached Section 1.3. of Annex XI is therefore rejected.

#### **3. Breach of Section 1.5. of Annex XI – Read-across**

84. In the present case, in order to satisfy the registration requirements for Section 8.6.2. of Annex IX (sub-chronic toxicity (90-day) study) and Section 8.7.2. of Annex IX (pre-natal developmental toxicity study) for the Substance, the Appellant proposed a read-across adaptation using the results of testing on the source substance which would be provided at a later date.

85. The general rules regarding the adaptation of information requirements using a grouping and/or read-across approach are set out in Section 1.5. of Annex XI:

*'1.5. Grouping of substances and read-across approach*

*Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. [...]' [emphasis added].*

86. When relying on a read-across adaptation to satisfy registration requirements, registrants are responsible for establishing that the adaptation complies with the conditions set out in Section 1.5. of Annex XI. Whilst registrants can expect a certain level of expertise within the Agency, it is not the task of the Agency to develop, or improve, read-across adaptations on their behalf. Registrants should, in particular, explain the premise for the read-across adaptation proposed, for example by creating an implicit or explicit hypothesis, and then show that the evidence supports that premise within the legal requirements of the REACH Regulation. It is then the Agency's task to examine whether the read-across adaptation proposed meets the requirements of the REACH Regulation (see Case A-004-2015, *Polynt*, Decision of the Board of Appeal of 19 October 2016, paragraph 123).
87. Pursuant to Section 1.5. of Annex XI, when applying an adaptation to read-across from one substance to another, registrants must establish, amongst other things, that the following two conditions are fulfilled. First, structural similarity of the source and target substance, and, second, toxicological properties of the target substance can be predicted from data on the source substance and, in this case, are '*likely to be similar*'.
88. As regards the first condition (structural similarity), the Contested Decision states that '*in the absence of detailed information on the composition and impurity profile of the source substance [the Agency] is unable to verify that there is structural similarity between the source and registered substances*'.
89. However, in the Defence the Agency stated that '*the structural similarity between the [Substance], i.e. the target substance, and the [source] substance, [...], has been established by the Appellant*'. From this it must be concluded that the first condition for a read-across adaptation is met.
90. As regards the second condition (similarity of toxicological properties), the Contested Decision states that '*no endpoint specific hypothesis establishing why the read-across can be performed has been provided and [...] the documentation included in the registration dossier does not contain information or evidence supporting the likelihood of similar toxicological properties for the endpoints repeated-dose toxicity and pre-natal developmental toxicity for the source and target substances*'.
91. In particular, the Agency explains in the Contested Decision that the Appellant's read-across adaptation contained insufficient information on sub-chronic toxicity and pre-natal developmental toxicity to demonstrate that the substances are likely to have similar properties for these two endpoints.
92. In this respect, it should be noted that the results of studies on sub-chronic toxicity and pre-natal developmental toxicity for the source substance were not available at the time the Contested Decision was adopted. In the absence of the studies on sub-chronic toxicity and pre-natal developmental toxicity for the source substance the Appellant provided other information to demonstrate that the toxicological properties of the Substance can be predicted from data on the source substance.

93. To support the read-across adaptation, the Appellant included (a) a comparison of structural similarities and endpoint specific properties using a model in the OECD QSAR toolbox, and (b) a proposal to perform an OECD TG 422 screening study on the Substance.

*(a) Information using an OECD QSAR model*

94. According to the Appellant, the similarities predicted by the OECD QSAR model suggests that the properties of the two substances are likely to be similar.
95. However, the read-across adaptation was not dismissed by the Agency on the grounds that the QSAR model was not relevant. The QSAR model is helpful in supporting the read-across adaptation proposed and may be helpful in the assessment of toxicological data on the source substance and the Substance. However, on its own, as a predictive model, it cannot overcome the weakness in the Appellant's read-across adaptation, namely the lack of data to allow a comparison of the toxicological properties of the two substances.
96. Care must be taken when applying one predictive tool (QSAR) to justify the use of another predictive tool (read-across). In this case, the QSAR model included in the registration update helps to support the read-across adaptation proposed by the Appellant. However, it is not sufficient to demonstrate that the read-across proposed actually works in practice. The problem of the lack of test data on the properties of the two substances cannot be overcome by reference to a QSAR model alone.
97. Consequently, the inclusion of information from an OECD QSAR model in the present case did not allow the conclusion to be reached that the toxicological properties of the Substance can be predicted from data on the source substance and, in this case, are *'likely to be similar'*.

*(b) Information on an OECD TG 422 study*

98. In its dossier update of 4 June 2015, the Appellant amended its read-across adaptation. With regard to the OECD TG 408 study the update stated that *'it is foreseen to additionally conduct an OECD [TG] 422 with the [Substance]. After availability of the running studies (OECD [TG] 422 with the [Substance] and OECD [TG] 408 with the source substance) the IUCLID dossier and this read-across justification will be updated accordingly'*. Similarly, with regard to the OECD TG 414 study, the update stated that *'it is foreseen to additionally conduct an OECD [TG] 422 with the [Substance]. After availability of the running studies (OECD [TG] 422 with the [Substance] and OECD [TG] 414 with the source substance) the IUCLID dossier and this read-across justification will be updated accordingly'*.
99. The Appellant argues that the Agency should have allowed the Appellant to perform an OECD TG 422 screening study on the Substance, then update its registration dossier with a revised read-across adaptation and, only if considered necessary by the Agency, perform an OECD TG 408 study and/or OECD TG 414 study on the Substance. The Appellant further argues that the Agency should have waited for the testing on the source substance to be completed before rejecting its read-across adaptation. An OECD TG 422 study is a registration requirement pursuant to Section 8.7.1. of Annex VIII. The Appellant stated during the proceedings that, in its registration dossier for the Substance, this endpoint was satisfied using a read-across from the results of an OECD TG 422 study on the source substance.
100. An OECD TG 422 study on the Substance could provide information relevant to the assessment of the repeated-dose toxicity and pre-natal developmental toxicity endpoints. This information may support the Appellant's argument that *'[b]ased on the limited difference between the source [substance's and the Substance's] chemical structures; and the overlap of physical/chemical properties; no major difference in repeated dose toxicity is to be expected'*.

101. However, the results of an OECD TG 422 study on the Substance may also support a finding that the source substance and the Substance do not have similar or predictable toxicological properties.
102. Consequently, before the results of the OECD TG 422 study on the Substance are known these results cannot be used to confirm the validity of the Appellant's read-across adaptation for the two higher tier tests in question.
103. The Agency did not therefore breach Section 1.5. of Annex XI by rejecting the Appellant's read-across adaptation despite the Appellant's proposal to perform an OECD TG 422 screening study on the Substance.

*(c) Conclusion on the alleged breach of Section 1.5. of Annex XI*

104. In view of the above, the Appellant has not demonstrated that the '*toxicological ... properties [of the Substance and the source substance] are likely to be similar or follow a regular pattern*'. The Agency therefore did not breach Section 1.5. of Annex XI in concluding in the Contested Decision that:  
  
*'...the evidence to support the likelihood of similar toxicological properties for the endpoints repeated-dose toxicity and pre-natal developmental toxicity is not yet available. For these reasons also, [the Agency] considers that it has not been demonstrated that the human health effects of the registered substance may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group, as required by Annex XI, Section 1.5. [...]'.*
105. At the time the Contested Decision was adopted the information on the source substance that could substantiate the proposed read-across adaptation was not available. Furthermore, an OECD TG 422 screening study on the Substance had not been conducted. As stated in paragraph 49 above, the Agency was not required to wait for the Appellant to update its read-across adaptation with additional information.
106. The Agency did not therefore commit an error in rejecting the proposed read-across adaptation. The absence of information on the systemic toxicity of the Substance prevents the conclusion being reached that the Substance and the source substance, although structurally similar, are likely to have similar or predictable toxicological properties, as is required by Section 1.5. of Annex XI.
107. At the time of the adoption of the Contested Decision, the dossiers for the two substances only included an OECD TG 422 screening study on the source substance to cover the two endpoints addressed in the Contested Decision (Sections 8.6.2. and 8.7.2. of Annex IX) and Section 8.7.1. of Annex VIII. There was therefore a largely empty matrix in the registration dossiers for both substances.
108. In view of the above, the Appellant's plea that the Agency breached Section 1.5. of Annex XI is rejected.

**D. Breach of the principle of legal certainty**

**Arguments of the Parties**

109. The Appellant argues that it is in a position of legal uncertainty because, if it submits a read-across adaptation for the relevant endpoints using the information obtained from the new tests on the source substance (OECD TG 408 and OECD TG 414) and/or the results of an OECD TG 422 study on the Substance, it does not know whether the test results will be sufficient to satisfy the Contested Decision. If the Agency rejects the adaptation, the Appellant may be subject to enforcement action.

110. The Agency argues that until the registration dossier includes relevant test results it does not know whether the Appellant's proposed and updated read-across adaptations can be accepted.

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

111. Article 42 ('*Check of information submitted and follow-up to dossier evaluation*') sets out the procedure for the follow-up to a testing proposal decision:

- '1. The Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary.*
- 2. Once the dossier evaluation is completed, the Agency shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. [...]'.*

112. The Appellant could perform the requested OECD TG 408 and 414 studies on the Substance as required by the Contested Decision. In this circumstance Article 42(2) applies and the dossier evaluation is complete.

113. As an alternative to performing the requested OECD TG 408 and 414 studies on the Substance the Contested Decision states that:

*'The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI [...]. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.*

*Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States'.*

114. At the hearing, the Appellant informed the Board of Appeal that the results of a sub-chronic toxicity study (OECD TG 408) and a pre-natal developmental toxicity study (OECD TG 414) on the source substance, as required in the testing proposal decision of 30 January 2015 on the source substance, are now available and have been included in a registration dossier update for the source substance.

115. If the Appellant, in order to meet the requirements in the Contested Decision, improves its read-across proposal by using the results of the sub-chronic toxicity study (OECD TG 408) and the pre-natal developmental toxicity study (OECD TG 414) performed on the source substance, the Agency will be required to assess this under Article 42(1). If the updated read-across adaptation is subsequently found to satisfy the information requests in the Contested Decision, then the Agency must proceed to the steps foreseen in Article 42(2).

116. However, if this information is not considered by the Agency to satisfy the Contested Decision, the test results on the source substance must be considered to be substantial new information and the Agency will be required to draft a new decision under Article 42(1) following the procedure set out in Articles 50 and 51 (see A-019-2013, *Solutia Europe*, Decision of the Board of Appeal of 29 July 2015, paragraphs 71 to 84).

117. In the present case, the results of the two studies on the source substance must be considered to be substantial new information for the following reasons:

- the Appellant was not in a position to submit the results of the OECD TG 408 and 414 studies on the source substance prior to the adoption of the Contested Decision because of the timing of the procedure for the evaluation of testing proposals on the source substance,

- submission of these results, to support the read-across adaptation, will require a detailed scientific assessment by the Agency using the scientific expertise available to it (see A-019-2013, *Solutia Europe*, Decision of the Board of Appeal of 29 July 2015, paragraph 81), and
  - the Agency's follow-up decision pursuant to Article 42(1) will not be merely confirmatory (see A-019-2013, *Solutia Europe*, Decision of the Board of Appeal of 29 July 2015, paragraphs 77 and 78).
118. The Appellant may also decide to strengthen its read-across adaptation further through the provision of the results of an OECD TG 422 screening study on the Substance. The Appellant's dossier for the Substance contained information from an OECD TG 422 screening study on the source substance. The Appellant has not yet performed an OECD TG 422 on the Substance. The Contested Decision acknowledges the Appellant's statement that when the OECD TG 422 study on the Substance becomes available it *'...may strengthen the overall read-across approaches for the endpoints under consideration'*.
119. If the Appellant chooses to update its read-across adaptation with the results of an OECD TG 422 screening study on the Substance, this information would be examined at the same time as the results of the OECD TG 408 and 414 studies on the source substance and following the same procedures set out in paragraphs 116 to 117 above.
120. In light of the above, the Appellant is not in a position of legal uncertainty. If the Agency rejects the Appellant's adaptation, updated with the results of the OECD TG 408 and 414 studies on the source substance, and possibly an OECD TG 422 screening study on the Substance, this will not automatically lead to enforcement action by the Member States. The procedures that need to be followed are clear. Furthermore, if the updated read-across adaptation is rejected by the Agency, the Appellant will have the opportunity, as a consequence of the application of Article 42(1), to present its arguments against such a conclusion.
121. In view of the above, the Appellant's plea regarding a breach of the principle of legal certainty is rejected.

## **E. Failure to take into account all the available information**

### **Arguments of the Parties**

122. The Appellant argues that the document entitled *'Justification of read across'*, submitted on 4 June 2015, contains a substantial amount of information addressing the Agency's concerns regarding the read-across adaptation. The Appellant argues that although this submission is acknowledged in the Contested Decision it was not assessed or taken into account by the Agency in its decision-making. In particular, this document addresses the points in the Contested Decision that *'no further details on the composition and impurity profile of the source substance are reported [and that] information on the composition and impurity profile of the source substance is essential'* and that *'no endpoint specific hypothesis [...] has been provided'*.
123. The Appellant further argues that the Agency also failed to take into account its proposal to conduct an OECD TG 422 study on the Substance, as part of a *'tiered approach'*, instead of the two tests requested in the Contested Decision.
124. The Appellant argues, moreover, that an OECD TG 422 study, pursuant to Section 8.7.1. of Annex VIII, is not missing from its registration dossier for the Substance. The Appellant satisfied the information requirement by reading across from the results of an OECD TG 422 study on the source substance.

125. The Agency argues that it is clear from the Contested Decision that it took into account all available information, including the registration update of 4 June 2015 and the Appellant's proposal to perform an OECD TG 422 study on the Substance.
126. The Agency argues that the Appellant is not required to submit a testing proposal prior to conducting an OECD TG 422 study. The Agency has no obligation to take a position on whether such a test is necessary for the requirements of Section 8.7.1. of Annex VIII.
127. The Agency argues that '*a study or studies of shorter duration, such as for instance a screening study for reproductive/developmental toxicity according to OECD TG 422, would be needed for the [Substance] to establish a basis for prediction*'.

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

128. When exercising its discretion, the Agency is required to take into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (see, by analogy, judgment of 7 March 2013, *Rütgers Germany and Others v ECHA*, T-96/10, EU:T:2013:109, paragraph 100, and Case A-001-2014, *CINIC Chemicals Europe*, Decision of the Board of Appeal of 10 June 2015, paragraph 74).
129. It is clear from the Contested Decision that the Agency did take into account the Appellant's dossier update of 4 June 2015. This document is discussed in detail in Section III of the Contested Decision. As noted at paragraph 89 above, the Agency stated during these appeal proceedings that the structural similarity of the Substance and the source substance has been established.
130. However, the Appellant did not address the flaw in its read-across adaptation, identified repeatedly by the Agency, namely that the Appellant had failed to demonstrate that the '*toxicological [...] properties are likely to be similar or follow a regular pattern*'. The update of 4 June 2015, including the proposal to conduct an OECD TG 422 study on the Substance, is not capable of changing this conclusion. As stated in paragraphs 100 to 102 above, until the results of an OECD TG 422 study on the Substance are known, no conclusion can be reached by the Agency on whether these results indicate that the relevant toxicological properties of the two substances are likely to be similar.
131. It is clear from the Contested Decision that the Agency considered the Appellant's proposal to perform an OECD TG 422 study on the Substance:  
*'[The Agency] acknowledges the further provided information and the Registrant's statement that the planned screening study for reproductive and developmental toxicity according to the OECD [TG] 422 with the [Substance] may strengthen the overall read-across approaches for the endpoints under considerations. However, [the Agency] points out that the evidence to support the likelihood of similar toxicological properties for the endpoints repeated-dose toxicity and pre-natal developmental toxicity is not yet available.'*
132. The Appellant's plea that the Agency failed to take into account its update of 4 June 2015 and the '*Justification of read-across*', including a proposal to perform an OECD TG 422 study on the Substance, is therefore rejected.

## **F. Breach of the duty to state reasons**

### **Arguments of the Parties**

133. The Appellant argues that the Agency breached its duty to state reasons set out in Article 130 of the REACH Regulation, Article 41 of the Charter of Fundamental Rights of the European Union, and Article 18 of the European Code of Good Administrative Behaviour. In particular, the Appellant argues that the Contested Decision does not allow the Appellant to understand why the proposed read-across adaptation was rejected.

134. The Agency argues that it is clear from the Contested Decision that the reason the read-across adaptation has been rejected is because the Appellant has not demonstrated that the *'toxicological [...] properties are likely to be similar or follow a regular pattern'*.
135. The Agency argues that in addition to the reasoning in the Contested Decision the Agency explained its reasoning in the exchange of views with the Appellant in the telephone conference of 21 May 2015.

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

136. Pursuant to Article 130 of the REACH Regulation and the second paragraph of Article 296 of the Treaty on the Functioning of the European Union ('TFEU'), the Agency must state the reasons for any decision it takes. The obligation for the Agency to state reasons for its decisions can also be found in Article 41(2)(c) of the Charter of Fundamental Rights of the European Union and Article 18 of the European Code of Good Administrative Behaviour.
137. A statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the European Union judicature to exercise its power of review (see judgment of 21 December 2016, *Club Hotel Loutraki and Others v Commission*, C-131/15 P, EU:C:2016:989, paragraph 46). Whether a statement of reasons is adequate depends on all the circumstances of a case, in particular, the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations (see judgment of 10 March 2016, *HeidelbergCement v Commission*, C-247/14 P, EU:C:2016:149, paragraph 16).
138. Section III of the Contested Decision contains clear reasoning for the rejection of the read-across adaptation. It states that the Appellant has not demonstrated that the *'toxicological [...] properties are likely to be similar or follow a regular pattern'*. These reasons were also explained to the Appellant during the decision-making process, for example in the draft decision and in the telephone conference of 21 May 2015.
139. The Appellant, however, seems rather to disagree with the conclusions reached by the Agency. In this respect, the duty to state reasons is different from the correctness of those reasons. The duty to state reasons is an essential procedural requirement which must be distinguished from the question whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue (see judgment of 14 October 2010, *Deutsche Telekom v Commission*, C-280/08 P, EU:C:2010:603, paragraph 130, and Case A-006-2012, *Momentive Specialty Chemicals*, Decision of the Board of Appeal of 13 February 2014, paragraph 113).
140. In light of the wording of the Contested Decision, as well as the Appellant's involvement in the decision-making process, the Appellant had sufficient information to enable it to understand the reasoning behind the Contested Decision.
141. The Appellant's plea that the Agency breached the duty to state reasons is therefore rejected.

### **G. Breach of the duty of good administration**

#### **Arguments of the Parties**

142. The Appellant argues that the Agency breached the duty of good administration, including the duty to act consistently, enshrined in the European Code of Good Administrative Behaviour. In particular, the Agency breached the duty of good

administration by conducting the testing proposal evaluation on the Substance without considering the testing proposals for the source substance. The time needed to perform the required OECD TG 408 and OECD TG 414 studies on the source substance and update its registration dossier with the results of those studies meant that those results could not be considered in the testing proposal evaluation for the Substance.

143. The Agency argues that *'[w]hile there would have been benefit to examine the testing proposals for both the registered and [source] substance including the applied read-across approach together, there was no possibility for [the Agency] to implement such an approach. In the registration dossier of the [source] substance, there has been no mentioning of the fact that these data and the data yet to be generated achieving for compliance may become relevant and used as well for other substances. There was thus no indication of possible inter-relations at the time when the examination of the testing proposals submitted for the similar [source] substance was initiated'*.
144. The Agency adds that it gave the Appellant *'specific and sufficient information on the regulatory work: it asked the Appellant to clarify the nature of the suggested testing of [a source] substance in its letter dated 30 April 2014 [...], was available to discuss the case of the registered substance in a conference call on 21 May 2015, and agreed to await a dossier update of the Appellant for an improved adaptation argument'*.

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

145. In the present case, the Appellant was given two years to generate the information on the two studies on the source substance required in the Agency's testing proposal decision for that substance. Before the results of these two studies are considered, in the context of the read-across adaptation, no conclusions can be drawn as to whether the read-across adaptation proposed will succeed as a result of that information. In light of this, as well as the primary objectives of the REACH Regulation of protection of human health and the environment, and the fact that any amended adaptation will be examined under Article 42 (paragraphs 115 to 120 above), the Agency did not need to wait for the results of the studies on the source substance to become available before deciding on the Appellant's registration dossier for the Substance (see also paragraph 49 above). The Agency did not therefore breach the duty of good administration.
146. Furthermore, the decisions requesting testing on the Substance and on the source substance are not inconsistent. In both cases the registrant is requested to perform testing on the substance which is the subject of the decision. Whilst the Appellant intended to perform testing on only one substance, it is currently not possible for a read-across adaptation to be accepted as the Appellant has not demonstrated that the *'toxicological [...] properties are likely to be similar or follow a regular pattern'* (see paragraphs 90 to 107 above).
147. The Appellant's plea that the Agency breached the duty of good administration is therefore rejected.

#### **H. Breach of Article 25 and the principle of proportionality**

148. The Parties' arguments on the pleas relating to Article 25 and the principle of proportionality overlap to a large extent. By raising these two pleas, the Appellant contests, in essence, the Agency's decision to reject the proposed read-across adaptation and the Agency's failure to consider the proposal to perform an OECD TG 422 study on the Substance as part of a step-wise or tiered approach. It is therefore appropriate to examine the two pleas together.

### Arguments of the Parties

149. The Appellant argues that the Agency breached Article 25 and the principle of proportionality by failing to consider alternatives to animal testing. The Agency should have:
- reviewed the Appellant's proposed read-across adaptation after the testing results on the source substance were made available, and
  - considered the Appellant's proposal to conduct an OECD TG 422 study on the Substance as part of a step-wise or tiered approach. Conducting an OECD TG 422 study *'would use at least twice as few animals compared to the number of animals to be used in the tests requested in the Contested Decision, and result in less stress to animals'*.
150. The Appellant argues that its proposal to perform an OECD TG 422 study on the Substance was not made to fill a data gap as the information requirement in Section 8.7.1. of Annex VIII had been met with an adaptation (a read-across to the results of an OECD TG 422 study on the source substance). The OECD TG 422 study was therefore not missing from the registration dossier for the Substance. The Appellant states that the proposal to perform an OECD TG 422 study on the Substance was offered as a compromise. The intention was to allay the Agency's concerns over the lack of evidence demonstrating the similar toxicity profiles of the two substances.
151. The Appellant claims that the Contested Decision means that both the source substance and the Substance will be subject to the same tests. Furthermore, the Contested Decision means it is not possible to wait for the results of testing on the source substance to complete the registration requirements for the relevant endpoints for the Substance.
152. The Agency argues that there is no breach of Article 25 or the principle of proportionality because the Appellant has not fulfilled the relevant standard information requirements and, in particular, did not provide a valid adaptation pursuant to Annex XI. Furthermore, waiting for the generation of data from testing, the results of which are unknown, which may potentially support an adaptation, cannot be considered to be a *'less onerous measure'*.
153. The Agency states that an OECD TG 422 screening study on the Substance is not a suitable alternative to the tests required in the Contested Decision. It lacks important *'key parameters'*, is of shorter duration, and is only capable of giving an insight into the developmental toxicity and repeated dose toxicity of a substance.
154. The Agency argues that an OECD TG 422 screening study is a standard information requirement under Section 8.7.1. of Annex VIII. It could have already been performed by the Appellant on the Substance. If it had been performed, the results may have contributed to a more rigorous justification for the read-across adaptation proposed. However, even though the possibility of conducting an OECD TG 422 screening study on the Substance was discussed at the teleconference with the Agency, the Appellant did not conduct such a screening study.
155. The Agency states that it will assess any new and substantive information in the follow up procedure under Article 42. The Appellant may therefore present an updated read-across adaptation instead of new experimental data if it so wishes.
156. The Intervener argues that the Agency must take an active role in ensuring that animal testing is conducted only as a last resort.
157. The Intervener argues that the Agency should have waited for the results of the OECD TG 408 and 414 studies on the source substance before adopting a decision requiring vertebrate animal testing on the Substance. If further information was required the Agency should have adopted a tiered approach.

### Findings of the Board of Appeal

158. Article 13 of the TFEU provides that '*in formulating and implementing the Union's agriculture, fisheries, transport, internal market [...] policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions [...].*'
159. Article 25(1) provides that '*in order to avoid animal testing, testing on vertebrate animals for the purposes of [the REACH] Regulation shall be undertaken only as a last resort [...].*'
160. 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 (see Case A-001-2014, *CINIC Chemicals Europe*, Decision of the Board of Appeal of 10 June 2015, paragraph 75).
161. Under dossier evaluation, which includes both compliance checks and the examination of testing proposals, the Agency can assess whether registration dossiers are in compliance with the requirements set out in the REACH Regulation. The discretionary powers of the Agency in this respect are limited to examining whether an adaptation submitted in a registration dossier complies with the rules set out in Annex XI or Column 2 of the testing Annexes. If the Agency finds that an adaptation does not comply with these rules, it must require the performance of the relevant test or tests in order to satisfy the registration requirements established in the REACH Regulation.
162. However, the incorrect rejection of a read-across adaptation by the Agency might lead to a registrant performing tests on vertebrate animals which may breach the principle of proportionality as well as the rules concerning vertebrate animal testing set out in Articles 13(1) and 25 (see Case A-004-2015, *Polynt*, Decision of the Board of Appeal of 19 October 2016, paragraphs 118 and 119).
163. It is therefore necessary to examine whether the Agency was justified in rejecting the read-across adaptation proposed by the Appellant on the ground that the conditions of Annex XI were not met.
164. As stated above (see paragraphs 84 to 108) the Agency did not commit an error in rejecting the Appellant's proposed read-across adaptation. As a consequence, the Agency had no discretion as to whether to request the Appellant to perform the sub-chronic toxicity study, which is a registration requirement under Section 8.6.2 of Annex IX, and the pre-natal developmental toxicity study, which is a registration requirement under Section 8.7.2. of Annex IX. Consequently, contrary to the Appellant's claims, the Agency did not breach Articles 13(1) and 25.
165. This conclusion would have been the same if the decision had been taken under Article 41 instead of Article 40 (see paragraphs 46 to 58 above).
166. With regard to the plea alleging a breach of the principle of proportionality, measures adopted by the European Union institutions must not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124 and the case-law cited; see also Case A-005-2011, *Honeywell Belgium*, Decision of the Board of Appeal of 29 April 2013, paragraphs 115 to 117).
167. The two requested studies constitute information required for registration purposes which must be provided under Sections 8.6.2. and 8.7.2. of Annex IX.

168. As stated in paragraphs 84 to 108 above, the Agency did not commit an error in rejecting the read-across adaptation proposed by the Appellant. In light of the primary objectives of the REACH Regulation of protection of human health and the environment, and the fact that any substantial new information will be examined under Article 42 (see paragraphs 115 to 120 and 145 above), the Agency did not need to wait for the results of the two studies on the source substance before evaluating the proposed read-across adaptation in the registration dossier for the Substance.
169. Once the Agency had rejected the proposed read-across adaptation it enjoyed no margin of discretion as to whether to request a sub-chronic toxicity study and a pre-natal developmental toxicity study. Consequently, it did not breach the principle of proportionality by requesting the studies to be performed (Case A-004-2015, *Polynt*, Decision of the Board of Appeal of 19 October 2016, paragraphs 138).
170. The Appellant's pleas that the Agency breached Article 25 and the principle of proportionality are therefore rejected.

## **I. Breach of the principle of legitimate expectations**

### **Arguments of the Parties**

171. The Appellant argues that the following statement from the Contested Decision breached its legitimate expectations as it contradicts the Agency's Guidance on Grouping of Substances and read-across approach (ECHA-13-R-02-EN, April 2013) (the 'read-across guidance'):
- '[The Agency] points out that the evidence to support the likelihood of similar toxicological properties for the endpoints repeated-dose toxicity and pre-natal developmental toxicity is not yet available. For these reasons also, [the Agency] considers that it has not been demonstrated that the human health effects of the registered substance may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group, as required by Annex XI, Section 1.5. [...].'*
172. The Appellant argues that the read-across guidance 'creates the legitimate expectation that read-across in the context of a testing proposal remains to be fully substantiated based on the results of the upcoming or pending testing'.
173. The Appellant argues that '*[the Agency's] indication that it would treat the adaptations as testing proposals on the [source] Substance created a legitimate expectations that the testing proposal on the registered substance would not result in the Contested Decision. At most, the Appellant would have expected for the evaluation of the Substance to be terminated, since the Agency had already opened the testing proposal on the same tests for the [source] Substance. The Appellant's legitimate expectations that the procedure on the Substance would be terminated were also strengthened by the third party consultation, organised by the Agency by reference to testing on the [source] Substance. At no point in the procedure was testing on the Substance itself subject to public consultation.'*
174. The Appellant claims that during the teleconference on 21 May 2015 the Agency created a legitimate expectation that further updates to the read-across adaptation in the registration dossier for the Substance would be considered.
175. The Agency argues that '*if there had been a reliable basis to predict properties between the [Substance] and the [source] substance, [the Agency] would have approved the proposed testing as plausible. However, in the case at hand, the conditions of Annex Section 1.5. of Annex XI were not met and therefore, the suggested adaptation could not be considered plausible'*.

176. The Agency further argues that *'this core reason of why the read-across is not plausible (the lack of a basis for comparing the toxicological profiles) is and remains clear and transparent in the Contested Decision'*.
177. The Agency moreover argues that it did not create any legitimate expectations in the read-across guidance.
178. Finally, the Agency argues that in its communications with the Appellant it clearly set out the reasoning behind the actions that it subsequently took. The Agency also states that the read-across guidance is clear and is consistent with the Agency's actions.

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

179. The right to rely on the principle of the protection of legitimate expectations presupposes that precise, unconditional and consistent assurances originating from authorised and reliable sources have been given to the person concerned by the competent authorities of the European Union. In accordance with settled case-law, that right applies to any individual in a situation in which an EU institution, body or agency, by giving that person precise assurances, has led them to entertain well-founded expectations. Precise, unconditional and consistent information, in whatever form it is given, constitutes such an assurance (see judgment of 13 June 2013, *HGA and Others v Commission*, Joined Cases C-630/11 P to C-633/11 P, EU:C:2013:387, paragraph 132).
180. The Appellant argues that the Agency breached its legitimate expectations which were based on (1) the Agency's communications, and (2) the Agency's read-across guidance.
181. As stated in paragraphs 128 to 132 above, the Agency did take into account the dossier update submitted by the Appellant on 4 June 2015. The Agency did not therefore act contrary to the assurance it gave to the Appellant during the teleconference on 21 May 2015 that it would take into account updates to the read-across adaptation.
182. The part of the read-across guidance referred to by the Appellant in its arguments reads:

*'3.10. Read-across and testing proposals*

*If testing proposals are included in the read-across approach, the information for the proposed source substance(s) are yet to be generated. Therefore, the read-across approach can only be considered at its best as plausible at this stage because the eventual acceptance of the read-across is dependent on the outcome of the proposed tests.'*
183. This extract of the read-across guidance does not state, or even imply, that decisions on a read-across adaptation will not be taken until the results of testing on a source substance are available. It states that in the absence of information on a source substance the Agency's assessment of a read-across adaptation will only be able to conclude on the plausibility of the read-across and not on its acceptance or rejection. The read-across guidance is silent on what this means for the acceptance or rejection of the read-across adaptation in question. This extract from the read-across guidance cannot therefore be construed as creating a legitimate expectation that the Agency will not conclude on a read-across adaptation for a target substance until the results of testing on a source substance are available.
184. In addition, the Agency also made it clear on several occasions, before the adoption of the Contested Decision, that information demonstrating that *'toxicological [...] properties are likely to be similar or follow a regular pattern'* was missing from the read-across adaptation and that the adaptation would be rejected in the absence of that information.

185. In view of the above, the Appellant's plea regarding the breach of its legitimate expectations is rejected.
186. As all of the Appellant's pleas have been rejected, the present appeal must be dismissed in its entirety.

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

187. 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) of the REACH Regulation or the appeal is decided in favour of an appellant.
188. As the appeal has been dismissed, the appeal fee will not be refunded.

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

189. The Contested Decision, upheld in the present appeal proceedings, required the Appellant to submit the required information by 3 May 2018 which is two years and seven days from the date of that Decision.
190. However, in light of the application of the suspensive effect provided for in Article 91(2), the information required in the Contested Decision must be submitted within two years and seven days from the date of notification of the Board of Appeal's decision in the present case.

On those grounds,

THE BOARD OF APPEAL

- 1. Dismisses the appeal.**
- 2. Decides that the information on sub-chronic toxicity and pre-natal developmental toxicity of the Substance requested in the Contested Decision must be submitted by 7 February 2020.**
- 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