EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

13 February 2014

(Evaluation – Compliance check – Adaptation of standard information requirements – Justification for the use of read-across – Duty to state reasons)

Case number	A-006-2012
Language of the case	English
Appellant	Momentive Specialty Chemicals Netherlands
Representative	Herbert Estreicher and Marcus Navin-Jones Keller and Heckman LLP Brussels Belgium
Contested decision	CCH-D-0000002304-84-04/F of 21 June 2012 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 41 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), Mia PAKARINEN (Legally Qualified Member and Rapporteur) and Andrew FASEY (Technically Qualified Member)

Registrar: Sari HAUKKA

gives the following

RELEVANT LEGISLATION

1. Article 13 of the Treaty on the Functioning of the European Union (hereinafter 'TFEU') provides:

   '*In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space 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 and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage.*'

2. Article 13(1) of the REACH Regulation provides:

   '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. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.'

3. Article 25(1) of the REACH Regulation provides:

   'In 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.'

4. Article 41(1)(a) and (b) and (3) of the REACH Regulation provides:

   '*1. The Agency may examine any registration in order to verify any of the following:*

   (a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;

   (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;

   […]

   3. On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, 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.'

5. Article 51(1) to (7) of the REACH Regulation provides:

'*1. The 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.*

2. Within 30 days of circulation, the Member States may propose amendments to the draft decision to the Agency.

3. *If the Agency does not receive any proposals, it shall take the decision in the version notified under paragraph 1.*

4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2.

5. The 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.

6. If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly.

7. If the Member State Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 133(3).'

6. Article 130 of the REACH Regulation provides:

'The competent authorities, the Agency and the Commission shall state the reasons for all decisions they take under this Regulation.'

7. Section 2 of Annex VI to the REACH Regulation provides:

'*For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.*

[…]

2.3.2. Nature of impurities, including isomers and by-products

[…]

2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

[…].'

8. Point 1.5 of Annex XI to the REACH Regulation provides:

'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. The Agency, after consulting with relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances sufficiently in advance of the first registration deadline for phase-in substances.

The similarities may be based on:

(1) a common functional group;

(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or

(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results should:

— be adequate for the purpose of classification and labelling and/or risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3),

— cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and

— adequate and reliable documentation of the applied method shall be provided.'

SUMMARY OF THE FACTS

Procedure before the Agency

9. On 22 February 2010, the Appellant submitted a registration dossier for the substance vinyl 2-ethylhexanoate (hereinafter 'VEHA' or 'the target substance') at the tonnage level of 10 to 100 tonnes per year.

10. On 21 June 2010, the Agency initiated a dossier compliance check of the Appellant's registration dossier for VEHA. Further to this, the Agency prepared a draft decision which was notified to the Appellant on 29 April 2011. The draft decision contained a number of information requirements. In particular, the Appellant was required to submit additional substance identification information, information on the physicochemical properties of VEHA, as well as toxicological information relating to skin sensitisation (Section 8.3 of Annex VII to the REACH Regulation), an in vitro gene mutation study in mammalian cells (Section 8.4.3 of Annex VIII), an in vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Section 8.4.2 of Annex VIII), and a 28-day repeated dose toxicity study (Section 8.6.1 of Annex VIII). In the letter of 29 April 2011 notifying the draft decision to the Appellant, the Appellant was given the opportunity to informally discuss the scientific rationale behind the draft decision. The Appellant did not however make use of this possibility.

11. For the information requirements concerning skin sensitisation, an in vitro gene mutation study in mammalian cells and the 28-day repeated dose toxicity study, the Appellant had proposed to read-across to the results of studies performed on the substance vinyl neodecanoate (hereinafter 'Veova 10'). The draft decision stated however that the conditions for a read-across adaptation had not been met and therefore requested the Appellant to provide information on the relevant studies. For the information relating to the in vitro cytogenicity study in mammalian cells or the in

vitro micronucleus study (Section 8.4.2 of Annex VIII), the draft decision stated that the Appellant had not provided the results of any studies or any justification for omitting the information.

12. On 26 May 2011, the Appellant submitted comments on the draft decision. In its comments the Appellant agreed to fulfil many of the information requirements set out in the draft decision. However, with respect to the information requirements for the skin sensitisation study, the in vitro gene mutation study in mammalian cells and the 28-day repeated dose toxicity study, the Appellant indicated that it would provide further justification for the read-across adaptation proposed and to that end attached a document entitled 'Documentation of read-across justification for vinyl esters'.

13. On 27 May 2011, the Appellant submitted an updated registration dossier to the Agency which increased the registration tonnage level to 100 to 1000 tonnes per year. The updated registration dossier also included a read-across adaptation for the in vitro cytogenicity study in mammalian cells or the in vitro micronucleus study (Section 8.4.2 of Annex VIII) information requirement. Following the Appellant's comments on the draft decision, the Agency amended the draft decision to reflect those comments in the statement of reasons. However, the Agency concluded that the read-across proposal still did not meet the requirements of Section 1.5 of Annex XI to the REACH Regulation and the draft decision was therefore not amended in this respect.

14. On 20 January 2012, the Agency notified the amended draft decision and the Appellant's comments to the Member States Competent Authorities (hereinafter the 'MSCAs') and invited them to propose amendments to the draft decision. Certain MSCAs submitted proposals for amendment to the draft decision with regards to the need to perform the 28-day repeated dose toxicity study (Section 8.6.1 of Annex VIII). The Agency did not, however, amend the draft decision in light of the proposals for amendment.

15. On 23 February 2012, the Agency notified the proposals for amendment to the Appellant and invited it to provide comments on the proposals, which it duly did on 26 March 2012.

16. On 5 March 2012, the Agency referred the draft decision to the Member State Committee (hereinafter the 'MSC'). On 14 March 2012, the Appellant was sent an invitation by the Agency to attend the MSC meeting. The Appellant did not however respond to that invitation.

17. On 26 April 2012, the MSC reached a unanimous agreement on the decision following the removal of the 28-day repeated dose toxicity study (Section 8.6.1 of Annex VIII) information requirement from the draft decision. The MSC also amended the draft decision to included reasoning in the statement of reasons regarding why the read-across adaptation proposed had been rejected.

18. On 21 June 2012, the Agency adopted the Contested Decision which requests the Appellant to provide inter alia information for VEHA on:

    - skin sensitisation (Section 8.3 of Annex VII; European Union (hereinafter 'EU') test method B.42.);
    - in vitro gene mutation in mammalian cells (Section 8.4.3 of Annex VIII, EU test method B.17); and
    - in vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Section 8.4.2 of Annex VIII; EU test method B.10 or draft Organisation for Economic Co-operation and Development (hereinafter 'OECD') guideline 487).

    The Appellant was required to submit this information in the form of an updated registration dossier by 21 June 2013.

19. With regards to the information requirements referred to in the previous paragraph the Appellant's registration dossier, as updated on 27 May 2011, did not contain the results of studies but instead relied on the use of read-across adaptions. For the information requirements for an in vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Section 8.4.2 of Annex VIII) the Appellant had proposed to read-across to information provided for the same endpoint for the substance vinyl neononanoate (hereinafter 'Veova 9'). For the information requirement for the skin sensitisation study (Section 8.3 of Annex VII) and an in vitro gene mutation study in mammalian cells (Section 8.4.3 of Annex VIII) the Appellant had proposed to read-across to information provided for the same endpoint for the substance Veova 10.

20. In the Contested Decision, however, the Appellant's proposed use of read-across was rejected. Points 2.6, 2.7 and 2.8 of Section III of the Contested Decision regarding each of the information requirements set out in paragraph 18 above provide the statement of reasons regarding why the read-across adaptation was rejected. In particular, each of those points states that the second introductory paragraph of both Annexes VII and VIII require registrants:

    '… to clearly state reasons for adapting the standard information according to the rules in Annex XI. As insufficient justification was provided for read-across, the requirements of Annex XI, Section 1.5 in conjunction with [the second introductory paragraph of Annex VII or VIII], of the REACH Regulation were not met. In addition to the lack of justification for the read-across, ECHA concludes that the read-across is insufficient for the following reasons:

    - [VEHA] is a mono-constituent substance, whereas the read-across substance appears to be a [Substance of Unknown or Variable composition, Complex reaction products or Biological materials (hereinafter 'UVCB')] composed of different isomers with different branching. In addition, information on the substance identity is lacking. Therefore structural similarity between the read-across and registered substances has not been established.
    - The registered substance has a distinct spectrum and potency of toxicological effects, compared to the read-across substance in other toxicological endpoints. Therefore toxicological similarity between the registered and read-across substances has not been established.

    Consequently, the read-across fails the criteria of Annex XI, section 1.5, and the information requirement […] is not fulfilled.'

Procedure before the Board of Appeal

21. On 20 September 2012, the Appellant lodged the present appeal at the Registry of the Board of Appeal in which it requested the Board of Appeal to annul the part of the Contested Decision that requires the Appellant to submit information on:

    - skin sensitisation (Section 8.3 of Annex VII; EU test method B.42.);
    - in vitro gene mutation in mammalian cells (Section 8.4.3 of Annex VIII; EU test method B.17); and
    - in vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Section 8.4.2 of Annex VIII; EU test method B.10 or draft OECD test guideline 487).

22. The Appellant also seeks a refund of the appeal fee.

23. On 9 November 2012, PETA International Science Consortium ('PISC') applied to intervene in the proceedings before the Board of Appeal in support of the Appellant. On 16 January 2013, the Board of Appeal rejected the application to intervene on the grounds that the Applicant had failed to demonstrate that, prior to the expiry of the time limit set for applications to intervene, it had legal personality, or that it possessed all of the characteristics which are at the foundation of such personality.

24. On 9 November 2012, the Appellant submitted additional documents and indicated that they were intended to supplement the Notice of Appeal. The Appellant informed the Board of Appeal that it had not been able to provide these documents earlier as the Appellant had only just received them following an access to documents request submitted under Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

25. On 17 December 2012, the Agency submitted its Defence.

26. By letter dated 23 January 2013, the Appellant was invited to submit its observations on the Agency's Defence and to respond to specific questions, including with regards to the relevance to the present proceedings of the documents submitted by the Appellant on 9 November 2012. On 7 March 2013, the Appellant submitted its observations.

27. On 19 March 2013, the Appellant was requested by the Board of Appeal to provide additional evidence related to its input to the decision-making process as well as all parts of its registration dossier relevant to the Contested Decision. On the same date, the Agency was requested by the Board of Appeal to provide all evidence related to the decision-making process and the draft decision which had not already been provided during the proceedings. On 8 April 2013, the Appellant and the Agency responded to the Board of Appeal's requests.

28. On 2 May 2013, the Agency was invited to reply to a number of questions regarding the Appellant's registration dossier updates. The Agency duly responded to those questions on 16 May 2013.

29. On 29 May 2013, the Parties were notified of the Board of Appeal's decision to close the written procedure. On 11 June 2013, the Appellant requested a hearing to be held. On 12 June 2013, the Agency informed the Board of Appeal that it did not request a hearing to be held.

30. In accordance with Article 13 of Commission Regulation (EC) No 771/2008 of 1 August 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'), following the Appellant's requests for a hearing to be held, the Parties were summoned to a hearing which was held on 27 September 2013. At the hearing, oral presentations were made by the Parties and the members of the Board of Appeal posed questions to the Parties.

REASONS

Admissibility of certain arguments and evidence lodged by the Appellant

31. In its Defence the Agency claimed that certain elements included in the Notice of Appeal should not be taken into account by the Board of Appeal.

32. The Agency firstly claims that the 14-day study on Veova 9 cited in the Notice of Appeal that was intended to clarify the similarity in toxicological profiles between the target substance and Veova 9 and Veova 10 (hereinafter the 'source substances') should be considered as new evidence and should have been included in the

Appellant's registration dossier if it considered it to be relevant. The Agency claims that the Appellant's registration dossier contained only a 14-day study on VEHA and not Veova 9. The Agency claims that it could not therefore have taken into account this information in the decision-making procedure.

33. In addition, the Agency considers that the opinions of the Appellant's experts attached to the Notice of Appeal must be considered as new information which cannot serve as a basis to assess the lawfulness of the Contested Decision.

34. The Board of Appeal notes that the provisions of Article 12(1) and (2) of the Rules of Procedure provide certain limitations regarding the introduction of new evidence and new pleas in law into appeal proceedings. These provisions seek to restrict the introduction of new evidence or pleas in law after the first exchange of written pleadings, unless the Board of Appeal decides that the delay in introducing further evidence or new pleas is duly justified or based on new matters of law or fact that come to light in the course of the proceedings.

35. The Board of Appeal observes that the Agency's objection to accepting the 14-day study on Veova 9 and the opinions annexed to the Notice of Appeal as evidence is not based on the limitation provided in the Rules of Procedure but rather on the reasoning that it constitutes new information which was not brought forward during the decision-making procedure before the Agency but only later in the context of the appeal proceedings.

36. The Board of Appeal observes that when examining whether evidence submitted in support of the Notice of Appeal that was not available to the Agency during the decision-making procedure leading to the adoption of the Contested Decision is admissible, the Board of Appeal needs to ascertain whether such evidence supports new facts or is supporting facts already alleged during the decision-making procedure before the Agency.

37. In the present case, the Board of Appeal considers that the 14-day study on Veova 9 and the opinions of the Appellant's experts were included in the Notice of Appeal to support the Appellant's claim made in the registration dossier that the source and target substances were sufficiently similar to allow read-across.

38. For the above reasons, the Board of Appeal finds that the 14-day study on Veova 9 and the opinions of the Appellant's experts annexed to the Notice of Appeal are admissible in the present proceedings.

Claims under Examination

39. The Appellant requests the Board of Appeal to partially annul the Contested Decision in so far as it requires the Appellant to submit the information referred to in paragraph 21 above.

40. In support of its claim that the Board of Appeal should partially annul the Contested Decision the Appellant presents five pleas. By its first plea the Appellant claims that, in rejecting the read-across adaptations, the Agency had incorrectly interpreted the requirements of the REACH Regulation. By its second plea the Appellant argues that the Contested Decision breached Article 25 of the REACH Regulation regarding testing on vertebrate animals being a 'last resort'. By its third plea the Appellant argues that the Agency breached its duty to state reasons. By its fourth plea the Appellant claims that the Contested Decision is manifestly disproportionate. Finally, by its fifth plea the Appellant claims that there was an irregularity in the procedure leading to the adoption of the Contested Decision.

Appellant's first plea alleging the Agency's incorrect interpretation of the requirements to permit a read-across adaptation

Arguments of the Parties

41. The Appellant claims that the Contested Decision was adopted in breach of the requirements of the REACH Regulation, as well as general principles of EU law, and is not scientifically justified, as the information requirements in the Contested Decision were satisfied by the Appellant through the use of read-across adaptations.

42. The Appellant claims that it is legally and scientifically justified in relying upon the read-across data submitted in the registration dossier. The Appellant claims that the question of whether a particular registrant can group substances and apply the read-across approach depends primarily on whether a substance is sufficiently similar in structure to another substance. The Appellant submits that the target substance is sufficiently similar in structure to the source substances to permit the use of read-across for the endpoints in question. The Appellant claims that in the Contested Decision the Agency concedes that the target and the source substances belong to the same common functional group and, as such, read-across is justified.

43. The Appellant submits that the Agency has provided no valid or justifiable grounds to deny the read-across approach set out in the registration dossier. The Appellant claims further that the substantive scientific grounds for not permitting read-across set out in the Contested Decision are inconsistent, illogical, and illegal. For example, the Appellant claims that the Agency did not reject or raise concerns regarding the use of read-across from the source substances to the target substance for ecotoxicological and environmental fate endpoints. In addition, the Appellant submits that there is no legal provision preventing a registrant from applying read-across between a mono-constituent substance and a UVCB.

44. The Appellant claims further that the Agency's general approach to read-across is inconsistent with, inter alia, the OECD approach and with a general body of recognised academic experts on read-across as supported by the opinions of the experts attached to the Notice of Appeal.

45. The Appellant also submits that, since it had clearly stated the reasons for relying on read-across, it had complied with the requirements of the second introductory paragraphs of both Annex VII and Annex VIII to the REACH Regulation. The Appellant claims that, in requiring sufficient justifications for the use of read-across, the Agency had acted beyond its legal authority.

46. The Appellant also claims that the Agency must itself obtain sufficient and adequate information regarding the proposed read-across and take all relevant information and considerations into account before drawing its conclusions and adopting its decision. In this respect, the Appellant claims that the Agency should, for example, have obtained opinions from external experts.

47. The Appellant further argues that the approach taken by the Agency did not balance the REACH objectives or consider the enhancement of competiveness and innovation before adopting the Contested Decision.

48. The Agency claims that, in accordance inter alia with Articles 1(3) and 41 of the REACH Regulation, it is the responsibility of registrants wishing to adapt a standard information requirement to apply the rules set out in Annex XI to the REACH Regulation. According to the Agency, registrants must justify proposed adaptations and subsequently, pursuant to Article 41(1)(b) of the REACH Regulation, it is for the Agency to examine the justifications for such adaptations.

49. In response to the Appellant's claims, the Agency submitted, in summary, that the Appellant's read-across adaptation of the standard information requirements does not comply with the rules set out in Section 1.5 of Annex XI to the REACH Regulation as:

    - there is no adequate and reliable documentation regarding the use of read-across. As a result, the Agency was not able to evaluate the read-across adaptation proposed and whether it complies with Section 1.5 of Annex XI;
    - the Appellant has not provided sufficient clarification as to the identity of the source substances and therefore structural similarity between the target and the source substances cannot be established;
    - the consideration of common functional groups is not in itself sufficient to establish structural similarity; a more fundamental examination of substance identity is required; and
    - the target substance has a distinct spectrum and potency of toxicological effects compared to the source substances and, as a consequence, it may not be possible to reliably predict the properties of the target substance from data on the properties of the source substances.

50. The Board of Appeal notes that in the Defence the Agency indicated that it had evaluated the justification for the read-across adaptations presented in the updated registration dossier to a certain extent but that where 'the information supporting a read-across approach is not adequate or reliable [the Agency] will not be in a position to evaluate the overall read-across approach'.

51. In the course of the proceedings the Agency confirmed that it does not dispute that read-across between UVCBs and mono-constituent substances is possible. However, the Agency claims that the Appellant did not adequately characterise the UVCBs being used for read-across, in other words the source substances, and so it was not possible to establish structural similarity with the target substance.

52. In response to the Appellant's claim that the Contested Decision is not in line with the OECD approach to read-across the Agency states that the use of read-across by other bodies such as the OECD is different to the use of read-across under the REACH Regulation.

Findings of the Board of Appeal

53. The Board of Appeal observes that in the present case the Appellant sought an adaptation to certain standard testing requirements by proposing to provide the required information by relying on a read-across approach. The Agency however rejected the Appellant's read-across proposal on the grounds that it did not meet the requirements of Section 1.5 of Annex XI to the REACH Regulation. The Board of Appeal notes that, in summary, the reasons set out in the Contested Decision (see paragraph 20 above) for rejecting the Appellant's proposed use of read-across are (i) failure to provide sufficient justifications for the use of read-across; (ii) failure to establish structural similarity between the target and source substances; and (iii) failure to establish toxicological similarity between the target and source substances.

54. In accordance with Article 13(1) of the REACH Regulation, a registrant may generate information on the intrinsic properties of the substance being registered by means other than tests provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, from information on structurally related substances (a grouping or read-across approach).

55. With regards to the information that must be included in a proposal for a read-across adaptation, the Board of Appeal observes that under the REACH Regulation, in particular Article 1(3) thereof, the burden of proof is on registrants to demonstrate that the substances that they market are safe to use. In addition, the Board of Appeal notes that, pursuant to Article 41(1)(b) of the REACH Regulation the Agency may examine any registration to verify that the adaptations of the standard information requirements and the related justifications comply with the relevant rules set out in Annexes VII to XI.

56. Furthermore, specifically with regards to the use of adaptations using the general rules contained in Annex XI, the second introductory paragraph of both Annexes VII and VIII require registrants to clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier. In addition, Section 1.5 of Annex XI provides that 'adequate and reliable documentation of the applied method shall be provided' for any read-across proposal.

57. The Appellant claims that the Agency had incorrectly rejected its read-across proposal as there is no legal requirement that a registrant should provide sufficient justification to support such a proposal. The Board of Appeal observes, however, that the Appellant nonetheless acknowledges that there is a requirement to clearly state the reasons for read-across. The Board of Appeal considers that, having regard in particular to the provisions of the REACH Regulation set out in paragraphs 55 and 56 above, the requirement to provide sufficient justification and the requirement to clearly state reasons are effectively the same. The Board of Appeal also notes that in its comments on the draft decision the Appellant did attempt to justify its adaptation proposal with a document entitled a 'Documentation of Read-Across Justification for Vinyl Esters'.

58. It is therefore clear from the above that 'adequate and reliable documentation of the applied method', as required by Section 1.5 of Annex XI to the REACH Regulation, must sufficiently support and explain the read-across proposal and must be clearly set out in the appropriate section of the registration dossier. Inclusion in the dossier of such information is essential to allow the Agency to carry out its role, set out in Article 41(1)(b) of the REACH Regulation, of evaluating whether the 'adaptations of standard information requirements and the related justifications […] comply with the rules governing such adaptations set out in Annexes VII to X and the general rules set out in Annex XI'.

59. The Board of Appeal also notes that in its initial registration dossier of 22 February 2010 the Appellant simply stated that 'Data from [Veova 10] is read-across to [VEHA] due to structural similarity'. The Board of Appeal considers that, whilst the length of a justification is not a measure of its quality, this statement did not meet the requirement that 'adequate and reliable documentation of the applied method shall be provided' and was clearly neither a sufficient justification nor a clear statement of reasons.

60. The Board of Appeal further observes that 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. The Board of Appeal considers that registrants should 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 registrants have in fact satisfactorily achieved this. The Board of Appeal also observes that, it is impossible for the Agency to inform individual registrants what exactly should be included in their justification for a read-across adaptation as it is the registrant who knows its substances best, who understands the basis for a read-across approach, and who has

the responsibility to communicate that information in such a manner that the Agency can then verify the approach proposed.

61. Nonetheless, the Board of Appeal observes that the Agency has made guidance available to help registrants set out and explain their read-across proposals in the best possible way. On this point, the Board of Appeal also notes that there is further guidance on the application of read-across available to registrants in the Agency's endpoint specific guidance. From the Appellant's statements at the oral hearing the Board of Appeal understands that the Appellant did not follow in its entirety the available guidance advising registrants how to present their read-across adaptations as it considered it to be very prescriptive. The Board of Appeal considers that in not following the available guidance the Appellant did not avail itself of a tool designed to help registrants to prepare and submit their read-across proposals in an effective way. The Board of Appeal observes that in so doing the Appellant may have required additional effort to justify its case compared with following the approach described in the guidance.

62. During the proceedings the Appellant also argued that in claiming that registrants must provide sufficient justification for their read-across proposal the Agency gives itself the scope to continually request whatever information it deems appropriate until it is fully content with the read-across proposal. In response to this argument, the Board of Appeal stresses that the Agency must act within the margins of its discretion and cannot make disproportionate requests for information that would be to the detriment of the objectives of the approach to read-across set out in the REACH Regulation. The Board of Appeal considers that the Agency needs to balance the objectives of the read-across provisions in the REACH Regulation, with the inherent uncertainty in any read-across adaptation and the need for predictive toxicology (and ecotoxicology) to be alert to the unusual or unexpected.

63. The Board of Appeal also observes that the problems identified by the Agency with the Appellant's read-across proposal were made clearly known to the Appellant during the decision-making process, most notably in the draft decision notified to it on 29 April 2011. The Appellant was therefore given the opportunity to remedy the shortcomings in its registration dossier before the adoption of the Contested Decision. Furthermore, the Board of Appeal notes that the Appellant was invited to participate in a teleconference to discuss the draft decision but that it did not make use of this opportunity. The Board of Appeal also notes that the Appellant was invited to attend the MSC meeting at which the draft decision, as amended following the comments of the MSCAs, was discussed but that the Appellant did not respond to the invitation nor attend the MSC meeting in question.

64. As stated above in paragraph 59, the Board of Appeal notes that, in effect, in the original registration dossier the Appellant had provided no justification for the read-across adaptation from the source substances to the target substance. The initial draft decision therefore reflected the fact that the Agency had little information on the read-across proposed. The Board of Appeal observes that, as a result, the Appellant received little input from the Agency regarding the validity of the read-across adaptation as the Agency had to base its decision on an absence of information rather than considering 'adequate and reliable documentation of the applied method' as required by Section 1.5 of Annex XI.

65. In light of the above, the Board of Appeal will examine whether the Agency's reasons for rejecting the read-across adaptation proposed were justified in the present case.

66. As a preliminary observation, the Board of Appeal notes that the first paragraph of Section 1.5 of Annex XI states that '[s]ubstances 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'. The Board of Appeal considers that the wording '… as a result of structural similarity …' means that the first criterion that needs to be met for a read-across adaptation to be possible is that structural similarity must be demonstrated. The second criterion that needs to be met for a read-across adaptation to be possible is that the '… properties are likely to be similar or follow a regular pattern …' must be demonstrated. Consequently, the third criterion that needs to be satisfied is that the similarity of properties is shown to be 'as a result of' structural similarity.

67. The Board of Appeal further notes that the first paragraph of Section 1.5 of Annex XI twice includes the word 'may' ('… may be considered as a group …' and '… may be predicted from data for reference substance(s) …') which further indicates that even if structural similarity and similarity of properties are demonstrated this is not necessarily sufficient, on its own, to justify a read-across adaptation. The Board of Appeal therefore concludes that the justification required includes the need to clearly set out the premise for the read-across adaptation so that the Agency can assess whether the structural similarity and likelihood of similarity (or regular pattern) of properties are demonstrated and, if so, that they are linked and can indeed be used as the basis for satisfying certain information requirements. The Board of Appeal also reiterates that 'adequate and reliable documentation of the applied method shall be provided' demonstrating how all the criteria in Section 1.5 of Annex XI have been met.

68. Since the demonstration of structural similarity between the target and source substances is a pre-requisite for a read-across adaptation, the Board of Appeal will firstly examine whether the Agency was justified in concluding that the Appellant had failed to establish structural similarity between the source and the target substances.

69. According to the Contested Decision information on the identity of the source substances, including the proportion of different isomers, was missing from the Appellant's registration dossier and, as a result, structural similarity between the target and source substances had not been established. For the target substance, according to Section II(1) of the Contested Decision, the Appellant's registration dossier did not contain information on spectral data (ultra-violet and nuclear magnetic resonance and/or mass spectra; Section 2.3.5 of Annex VI to the REACH Regulation) and chromatographic data (Section 2.3.6 of Annex VI to the REACH Regulation). The information requirements for the target substance, set out in Section II(1) of the Contested Decision, are uncontested in the present proceedings.

70. The Agency considers that sufficient substance identity information on the source substance(s) is required so that the structural similarity between the source and target substance(s) can be established by registrants. The Appellant argues, however, that structural similarity can be established without this substance identity information and stated during the oral hearing that this is not a case on substance identity. In particular, the Appellant claims that the target and source substances share the same functional group and therefore structural similarity has been established. The Appellant also supported its case in the updated registration dossier with a comparison of the structures of the source and target substances and, during the present proceedings, presented three opinions by experts to support its case. During the proceedings, the Agency supported its concerns with regard to structural similarity by stating that the consideration of common functional groups is not in itself sufficient to establish structural similarity.

71. The Board of Appeal agrees with the Appellant that it is not necessary in every case to have all the substance identity information set out in Section 2 of Annex VI on all the target and source substances concerned in order to demonstrate structural similarity. The Board of Appeal also notes that in some cases additional or different information may be required (for example, identification of hydrocarbon classes and their variability in certain UVCBs) in order to demonstrate structural similarity for read-

across purposes. Furthermore, in some cases, information that is not directly related to substance identity may be a factor in considering the validity of a read-across adaptation. For example, for ecotoxicological endpoints the fate and behaviour of a substance is largely governed by its inherent physicochemical properties; as a result the partition coefficient n-octanol/water may be an important consideration. The amount of information required to demonstrate structural similarity therefore depends on the case at issue. With this in mind, the Board of Appeal will examine whether, in the present case, the Agency was justified in concluding that structural similarity had not been demonstrated.

72. Firstly, the Board of Appeal observes that establishing structural similarity between a UVCB and a mono-constituent substance, whilst certainly possible, does bring with it certain challenges. As noted by one of the Appellant's experts '… the vinyl esters may be considered to be, in some circumstances, UVCBs. This is analogous to a situation where a compound may be manufactured and have one or more impurities present. An impurity, if demonstrating significant differences in chemical structure from the main constituent may alter the toxicity in a test.' Whilst the expert concludes that the changes to the alkyl chain are unlikely to affect the robustness of the category concerned this does indicate that the Agency's concern with regard to structural similarity is a credible one. Furthermore, as implied above, impurities are not indicated for UVCBs. In the absence of information on impurities, the Agency had to consider whether it needed more detailed information regarding the isomers of the vinyl esters.

73. Secondly, the Agency also linked its concerns with regard to the structural similarity of the target and source substances to the toxicological properties of the substances concerned. In particular, in the Contested Decision, the Agency pointed to the differences in the results of the repeated dose toxicity studies for the target and source substances. Such a concern was also acknowledged in one of the opinions provided by the Appellant's experts, which stated that '… minor structural differences […] may certainly translate into minor differences regarding toxicokinetics … which in turn may result in minor differences regarding the potencies of specific effects […] may translate into differences in the presence of certain effects'. Whilst the expert concludes that the read-across approach taken is mechanistically sound, this demonstrates to the Board of Appeal that the Agency had further grounds to question the structural similarity of the substances concerned in light of the possible impact on toxicity.

74. Thirdly, during the proceedings, the Agency argued that it was justified in concluding that additional information on the structure(s) of the source substances was required to demonstrate structural similarity by reference to the inconsistencies in the structures of the source substances in various Annexes to the Notice of Appeal. For example, the justification for the read-across in the updated registration dossier included two structures for each of the two source substances whilst the 'Diagramatic illustration of VEHA, Veova 9 and Veova 10', annexed to the Notice of Appeal, while purporting to show the structural similarity between the substances, included 22 different structures for Veova 10, and 17 for Veova 9. The Agency further noted that these different structures represent the different structural isomers of the vinyl esters resulting from variability of the alkyl chain, and does not take into account any potential impurities or non-vinyl ester constituents, which may have other functional groups.

75. Fourthly, the Board of Appeal notes that the opinions of the Appellant's experts regarding the structural similarity issue, whilst strongly supporting the read-across adaptation, nonetheless identify a degree of uncertainty. For example, the opinions state that '… the differences in structure […] are unlikely to significantly alter the likelihood or quantity of toxic metabolites', and '… based on the outcome of the modelling and taking into account other relevant weight of evidence …'. Whilst there is

a degree of uncertainty with any read-across adaptation, these opinions do not however demonstrate that the Agency was incorrect in considering that further information with regard to the structural similarity of the substances in question was required.

76. Fifthly, at the oral hearing, the expert present as a representative of the Appellant informed the Board of Appeal that the basis for his expert report was the information presented in the Appellant's justification for the read-across submitted in the updated registration dossier, and certain robust study summaries. During the oral hearing it became clear to the Board of Appeal that the Appellant's expert had not been provided with the full registration dossier submitted for the target substance and had not therefore considered all the information on the target and source substances that must necessarily be considered by the Agency in its evaluation compliance checks.

77. The Board of Appeal finds that the opinion of the expert present at the oral hearing as a representative of the Appellant did not evaluate the read-across proposal according to the requirements of Section 1.5 of Annex XI and the REACH Regulation more widely. In other words it is clear that the Agency's task in compliance checks of adaptations to standard data requirements is different from that conducted by the Appellant's expert in this case. In this respect, the Board of Appeal notes that one of the other expert opinions attached to the Notice of Appeal states that '… there is no reason to dismiss the possibilities of performing read-across on this group of vinyl esters.' The Board of Appeal observes that the Agency's task is not to consider the possibilities of read-across but to come to a conclusion on whether adaptations to standard data requirements satisfy the requirements of the REACH Regulation. Furthermore, the Contested Decision does not state that read-across is not possible in the present case; rather it states that the Appellant has failed to demonstrate that the adaptation proposal satisfies the requirements set out in Section 1.5 of Annex XI. The Board of Appeal also observes that the OECD's approach to read-across, the assessments it makes, and the information on which those assessments are based, is different to that of the Agency and the requirements of the REACH Regulation.

78. In light of the above, the Board of Appeal finds that the Agency was justified in concluding in the Contested Decision that structural similarity between the target and source substances had not been demonstrated.

79. The Board of Appeal will next examine whether the Agency was justified in concluding that similarity of properties had not been demonstrated.

80. According to the Contested Decision the 'distinct spectrum and potency of toxicological effects' related to other endpoints had not been adequately addressed in the read-across adaptation proposal; as a result the Contested Decision concludes that toxicological similarity between the target and source substances had not been established. In particular, the Contested Decision states that '… the available information on the registered substance indicates it has a distinct spectrum and potency of toxicological effects compared to the read-across substances, and these differences are not explained satisfactorily. For example, in a 14-day repeated dose toxicity study, the registered substance showed different potency and organ-specific effects (neurotoxicity, haematotoxicity, and absence of renal hyaline droplets) to that observed with the read-across substances. These effects are not addressed by the read-across argument.'

81. The Appellant claims in essence however that the results of the 14-day repeated dose toxicity study do not indicate that the target substance has a distinct spectrum and potency of toxicological effects compared to the source substances.

82. Whilst there is nothing in the REACH Regulation that specifically indicates the criterion of 'a distinct spectrum and potency of toxicological effects', the Board of Appeal understands this as referring to the first sentence of Section 1.5 of Annex XI which states that '[s]ubstances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern …'; in other words the second criterion identified by the Board of Appeal in paragraph 66 above.

83. As a preliminary remark, the Board of Appeal agrees with the Appellant's argument that read-across adaptations are endpoint specific, reflecting, amongst other things, the relevant route of exposure, modes of action and adverse outcome pathways. However, bearing in mind that the primary objective of the REACH Regulation is the protection of human health and the environment (see, for example, the Board of Appeal's Decision of 19 June 2013 in Case A-001-2012, paragraph 103), registrants and the Agency should take into account any other information, for example on other endpoints, that may be relevant to a read-across adaptation particularly with regard to the potentially hazardous properties of a substance. With this in mind, the Board of Appeal considers that in this particular case, when evaluating the read-across adaptations, the Agency was correct in identifying that the results from repeated dose toxicity studies on the target and source substances needed to be explained as they may indicate a difference in toxicity between the target and source substances for the endpoints subject to read-across adaptations. The Board of Appeal notes that the Agency has also identified in the present proceedings other test results, for example on prenatal developmental toxicity, which gives rise to questions with regard to the hazardous properties of the target and source substances.

84. In addition, the Board of Appeal notes that the opinions of the Appellant's experts regarding the toxicity issue, whilst strongly supporting the read-across adaptation and the similarity of toxicological properties, identify a degree of uncertainty. For example, the opinions state that '… from the chemical viewpoint the differences are only minor […] quite similar physicochemical properties …', '… while there are alternative metabolic routes […] there is evidence that these do not contribute significantly to the toxicity profile …', and '… the large degree of similarity in the toxicological profile …'. One of the experts also identifies in its opinion attached to the Notice of Appeal that there are two possible alternatives to explain skin sensitisation, gene mutation and cytogenetic effects of vinyl esters. One of the opinions also referred to the fact that vinyl esters metabolise to acetaldehyde which is known to be genotoxic.

85. As stated in paragraph 62 above, whilst there is a degree of uncertainty with all read-across adaptations, the challenge for the Agency is in balancing the objectives of the read-across provisions in the REACH Regulation, with that inherent uncertainty, and the need for predictive toxicology (and ecotoxicology) to be alert to the unusual or unexpected.

86. The Board of Appeal observes that one of the Appellant's experts stated that '… with regard to […] repeated dose toxicity studies […] there are inevitably minor differences […] however there is a consistent pattern to chronic toxic effects'. The Board of Appeal notes that the justification for the read-across in the updated registration dossier concentrates on the similarity of 'biological effects' and does not adequately address a 'consistent pattern' to chronic toxic effects as mentioned above. Section 1.5 of Annex XI clearly distinguishes between the similarity of properties and a regular pattern of properties as the results for read-across purposes will be different.

87. The Board of Appeal further considers that these potential toxicological differences give further support to the Agency's finding that further justification of the structural similarity of the target and source substances is required as this may help to explain differences seen in the toxicity for different endpoints for different substances. The Board of Appeal considers that the Agency was therefore justified in seeking additional

information to examine whether there may be some structural differences between the substances that could lead to a difference in toxicity between them for certain endpoints.

88. In light of the above, the Board of Appeal finds that the Agency was justified in concluding in the Contested Decision that toxicological similarity between the target and source substances had not been demonstrated.

89. The Board of Appeal finds that in the absence of information on structural similarity and the likelihood of similarity of toxicological properties the Agency was justified in concluding that the criterion of 'adequate and reliable information of the applied method' was not met and that, therefore, the case for the read-across adaptation had not been justified according to the requirements set out in Section 1.5 of Annex XI.

90. In conclusion, the Board of Appeal finds that the Agency was justified in concluding that the Appellant had not demonstrated the structural similarity and similarity of toxicological properties of the target and source substances, and that the read-across adaptation had not been sufficiently justified in order to meet the requirements of Section 1.5 of Annex XI. The Board of Appeal finds therefore that the Appellant has not demonstrated that the Agency acted illegally in its interpretation of the REACH Regulation and the requirements to permit read-across. The Appellant's arguments in this respect must therefore be dismissed as unfounded.

Appellant's second plea alleging a violation of Article 25 of the REACH Regulation

Arguments of the parties

91. The Appellant claims that, pursuant to Article 25(1) of the REACH Regulation, it was legally obliged to submit and rely upon read-across data in order to, amongst other things, avoid vertebrate animal testing, which should only be undertaken as a last resort.

92. In support of its plea, the Appellant states further that according to Article 13(1) of the REACH Regulation, for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests for example through the use of read-across. In addition, the Appellant claims that Article 13 of the REACH Regulation and Directive 2010/63/EU 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) set out the 'three Rs principle' according to which animals should not be used where a non-animal method would suffice (replacement), as few animals as possible should be used (reduction), and the least amount of suffering should be caused (refinement).

93. The Appellant claims further that by interpreting the provisions of the REACH Regulation on read-across as narrowly and restrictively as possible the Agency has acted inconsistently with, and in breach of, the REACH requirements concerning testing on vertebrate animals.

94. The Appellant also claims that the Agency failed to take into consideration the principle of animal welfare before adopting the Contested Decision. The Appellant states that the Agency is obliged under Article 13 TFEU to have 'full regard to the welfare requirements of animals' since they are 'sentient beings'. The Appellant also claims that, pursuant to Article 25 of the REACH Regulation, the Agency is required to ensure that animal testing is undertaken only as a last resort.

95. The Agency claims that, whilst it acknowledges that one of the aims of the REACH Regulation is to reduce unnecessary testing by promoting the use of alternative test methods and non-test data, it is the responsibility of the registrant to build adaption arguments, where necessary, to comply with the rules set out in Annex XI to the REACH Regulation. According to the Agency, registrants must demonstrate that adaptations from the standard information requirements are adequate to fulfil these information requirements. In this respect, the Agency considers that in this particular case the Appellant failed to satisfy the conditions set out in Section 1.5 of Annex XI for adaptation of the standard testing regime.

Findings of the Board of Appeal

96. The Board of Appeal observes that Article 13 of the TFEU provides inter alia that in formulating and implementing the EU's internal market policies the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals. At the time of adoption of the REACH Regulation, identical wording to Article 13 TFEU was found in Protocol 33 on the protection and welfare of animals, which, pursuant to the Treaty of Amsterdam, was annexed to the Treaty establishing the European Community. In this respect, the Board of Appeal observes that the REACH Regulation contains a number of provisions which take into account the welfare of animals. This includes, for example, Article 25(1) as well as the provisions on the use of read-across adaptations to meet standard information requirements.

97. The Board of Appeal also observes that animal welfare concerns must be balanced against the other objectives of the REACH Regulation. In this respect, the Board of Appeal also recalls that it is apparent from Article 1(1) of the REACH Regulation that that Regulation seeks to ensure a high level of protection of human health and the environment including the promotion of alternative methods for assessment of the hazardous properties of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Regard being had to Recital 16 of the preamble to the REACH Regulation, as mentioned in paragraph 83 above, the legislature established, as the main objective, the first of those three objectives, namely to ensure a high level of protection of human health and the environment. That objective should be achieved by the registration obligation imposed on manufacturers and importers, which includes the obligation to generate data on the properties of substances which they manufacture or import, to use those data to assess the risks related to those substances, and to develop and recommend appropriate risk management measures (see, to that effect, Case C-558/07 *S.P.C.M. and Others*, [2009] ECR I-5783, paragraphs 45 and 46).

98. The Board of Appeal observes further that one of the main purposes of the provisions of the REACH Regulation related to read-across is to ensure that testing on vertebrate animals is undertaken only as a last resort. In the present case, which concerned a standard information requirement, Article 13(1) of the REACH Regulation requires the use of read-across if the conditions of Section 1.5 of Annex XI are met. The Agency's role in this respect is to verify whether a registrant's proposed use of read-across 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 (see also the Board of Appeal's Decision of 19 June 2013 in Case A-001-2012 Dow Benelux, paragraph 116). 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.

99. The Appellant claims that pursuant to Article 25 of the REACH Regulation it was legally obliged to use read-across to satisfy the endpoints at issue. The Board of Appeal notes, however, that part of a registrant's duty to comply with Article 25 of the REACH Regulation includes not only identifying the possibility to use read-across but also to provide sufficient justification in order to meet the requirements of Section 1.5 of Annex XI. As stated in paragraphs 54 to 58 above, it is not sufficient for registrants to merely indicate that they have opted for the use of read-across to meet an information requirement. In order for a read-across proposal to be accepted it must comply with the provisions of Section 1.5 of Annex XI to the REACH Regulation. As stated above in paragraph 90, the Board of Appeal has found that the Agency was justified in concluding that the Appellant had not demonstrated the structural similarity and similarity of toxicological properties of the target and source substances, and that the read-across adaptation had not been justified according to the requirements set out in Section 1.5 of Annex XI.

100. In view of the above, the Appellant's claim that the Agency violated Article 25 of the REACH Regulation must be rejected as unfounded.

Appellant's third plea alleging the violation of the Agency's duty to state reasons for the Contested Decision

Arguments of the Parties

101. The Appellant claims that the Contested Decision breached Article 130 of the REACH Regulation regarding the duty to state reasons. In particular, the Appellant claims that there are no reasons in the Contested Decision as to whether the Agency considers that VEHA, the target substance, is or is not sufficiently structurally similar to the source substance(s) to permit read-across and if so what the structural differences are which prevent read-across. The Appellant also claims that there is no reasoning as to why the read-across proposal in the registration dossier was accepted by the Agency for some endpoints, notably regarding ecotoxicity, whereas the read-across for other endpoints was not.

102. The Appellant also claims that the statements made in the Contested Decision are self-conflicting and self-contradictory and that the statements made in the Contested Decision that the Appellant is required to provide 'sufficient justification' for providing read-across data are not correct in law.

103. The Agency argues in particular that it has sufficiently justified in the Contested Decision why the Appellant's proposed use of read-across did not meet the requirements of Section 1.5 of Annex XI to the REACH Regulation.

Findings of the Board of Appeal

104. Pursuant to Article 130 of the REACH Regulation the Agency shall state the reasons for the decisions it takes under that Regulation. The Board of Appeal considers that this duty to state reasons has the same scope as that under paragraph 2 of Article 296 TFEU. According to the case-law of the European Courts, pursuant to that provision, the reasons given in the Contested Decision must show in a clear and unequivocal manner the reasoning of the Agency so that the persons concerned by the act are able to ascertain whether the measure is well founded and to enable the legality of the act to be reviewed. Furthermore, the requirements to be satisfied by the statement of reasons depend on the circumstances of each case. In addition, the question of whether a statement of reasons complies with Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules

governing the matter (see, for example, Case C-367/95 P *Commission v Sytraval and Brink's France,* [1998] ECR I–1719, paragraph 63).

105. The parts of the reasoning of the Contested Decision relevant for the present proceedings are set out in paragraph 20 above. The Board of Appeal also notes that similar reasoning was contained in the draft decisions of 29 April 2011 and 20 January 2012. The Board of Appeal notes that the Contested Decision and the draft decision of 20 January 2012 also contain observations on the Appellant's comments provided on the initial draft decision of 29 April 2011. In this respect, the Board of Appeal observes that where the persons concerned are involved in the process by which a measure comes about, the requirement to state reasons may be circumscribed, since those persons acquire information through their involvement (see for example Case T-504/93 *Tiercé Ladbroke v Commission,* [1997] ECR II-923, paragraph 52).

106. In support of its plea that the Agency breached its duty to state reasons, the Appellant argues inter alia that no reasons were provided as to why read-across was accepted for some endpoints, specifically for ecotoxicological endpoints, but not for others. The Board of Appeal considers, however, that the Agency's duty to provide reasons extends only to those measures contained in a contested decision and that adversely affect the addressee thereof. The Agency was therefore not obliged to provide reasons regarding why certain issues are not included in the Contested Decision. In the present case, the Contested Decision does not contain the requirement for the Appellant to submit additional information with regard to ecotoxicological endpoints or any other statement in that regard which would have adversely affected the Appellant. Consequently, the Agency was not required to provide reasons in the Contested Decision for not requesting information on the ecotoxicological endpoints. The Appellant's arguments in this respect cannot therefore be accepted.

107. With regards to the adequacy of the reasoning contained in the Contested Decision, Section III of the Contested Decision states firstly that the justification provided by the Appellant in its registration dossier for the read-across adaptation as regards skin sensitisation and the two in vitro studies, is insufficient. The Board of Appeal considers that whilst there is little additional reasoning to substantiate this part of the Contested Decision, without structural similarity or similarity of toxicological properties having been demonstrated, as identified in the Contested Decision (see paragraphs 53 to 90 above), it was almost impossible for the Agency to identify, beyond these failings, what is additionally required to justify the read-across proposal. Furthermore, the Board of Appeal observes that even with information on structural similarity and similarity of toxicological properties the Appellant would still be required to document the applied method; the task of the Agency would then be to consider whether the case for read-across had been sufficiently justified.

108. The Appellant also claims that there are no substantive reasons in the Contested Decision detailing whether the Agency considers VEHA to be sufficiently structurally similar to the source substances to permit read-across and if not, what the structural differences are which prevent read-across. The Board of Appeal considers, however, that it is the task of the Appellant to demonstrate that the substances in question are structurally similar and for the Agency to judge inter alia whether the facts and evidence presented are convincing in this regard. It cannot however be required from the Agency that it would in every case, when rejecting a read-across adaptation on the grounds that structural similarity has not been demonstrated, describe in detail what needs to be included in order for structural similarity to be demonstrated. In this regard the Board of Appeal notes that in some cases structural similarity cannot be demonstrated regardless of the amount and quality of the information provided and in others the Agency will only know that the proposal is justified once a complete explanation is received. As a result, a reference to the key findings that prevented the Agency from concluding that the substances were structurally similar can be sufficient,

particularly taking into account that, structural similarity is only one of the factors that need to be addressed in order for a read-across adaptation to be accepted. The Board of Appeal also observes that, as explained in paragraph 60 above, it is impossible for the Agency to inform a registrant what exactly needs to go in its read-across adaptation as it is the registrant who knows its substances best, who understands the basis for its read-across approach, and who has the responsibility to communicate that information in such a manner that the Agency can then verify the approach proposed. The Appellant's arguments in this respect cannot therefore be accepted.

109. In addition, according to the Contested Decision, the target substance has a distinct spectrum and potency of toxicological effects compared to the source substances and therefore toxicological similarity between the target and source substances has not been established. An example of an effect identified by the Agency that is not addressed in the read-across arguments provided by the registrant is the 14-day repeated dose toxicity study in which the target substance showed different potency and organ-specific effects to those observed with the source substances. As a result of the Agency's findings, the Contested Decision concluded that it is not possible to conclude that the requirement in Section 1.5 of Annex XI to the REACH Regulation that properties are likely to be similar or follow a regular pattern has been met.

110. The Board of Appeal also finds that the Contested Decision in this regard clearly stated the need for further explanations regarding the 'distinct spectrum and potency of toxicological effects' and why such explanations were required.

111. With regard to the Appellant's argument contesting the requirement to provide sufficient justification, the Board of Appeal has found (see paragraphs 55 to 58 above) that 'adequate and reliable documentation of the applied method', as required by Section 1.5 of Annex XI of the REACH Regulation, must sufficiently support and explain the read-across and must be clearly set out in the appropriate section of the registration dossier. The Appellant's arguments in this respect cannot therefore be accepted.

112. In conclusion, when examining the reasoning included in the Contested Decision, all the factors pertaining to this particular case, and in particular taking into account the shortcomings in the registration dossier in demonstrating structural similarity, the similarity of properties and justification for the read-across proposed, the reasoning in the Contested Decision was sufficient to allow the Appellant to understand the Agency's reasons for the Contested Decision and to allow the legality of that decision to be reviewed.

113. The Board of Appeal also highlights that, according to the case-law of the European Courts, the duty to state reasons in decisions is an essential procedural requirement which must be distinguished from the question of whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue. The reasoning of a decision consists of a formal statement of the grounds on which that decision is based. If those grounds are vitiated by errors, those errors will vitiate the substantive legality of the decision, but not the statement of reasons in it, which may be adequate even though it sets out reasons which are incorrect (see for example Case C-413/06 P *Bertelsmann and Sony Corporation of America v Impala,* [2008] ECR I-4951, paragraph 181). Nonetheless, the Board of Appeal has already concluded in paragraphs 78, 88 and 90 that the Agency was justified in concluding that structural similarity and the similarity of properties of the target and source substances had not been demonstrated, and that the adaptation had not been sufficiently justified according to the requirements of Section 1.5 of Annex XI.

114. Consequently, the Appellant's arguments related to the legal and scientific accuracy of the reasons set out in the Contested Decision, examined above in paragraphs 53 to 90, cannot call into question the finding that the Agency had not violated its duty to state reasons for the Contested Decision.

115. For the above reasons, the Board of Appeal considers that in the present case the Agency has not violated the requirement to provide a statement of reasons for the Contested Decision. The Appellant's third plea must therefore be dismissed.

Appellant's fourth plea alleging the manifest disproportionality of the Contested Decision

Arguments of the Parties

116. The Appellant claims that the consequences of the Agency requiring vertebrate animal testing on a substance which is, in its opinion, so similar in structure to the source substances will, when extrapolated and extended to all relevant REACH registered substances mean that the sacrifice of millions of vertebrate animals for no scientific or other benefit is a manifestly disproportionate act.

117. The Agency argues in particular that in making discretionary policy choices, taking into account and balancing several interests, it has a wide discretionary power provided that the decision taken, as in the present case, is appropriate and necessary in order to achieve the objectives legitimately pursued by the REACH Regulation.

Findings of the Board of Appeal

118. The contested part of the Contested Decision addresses standard information requirements for the relevant tonnage band. According to the REACH Regulation, these information requirements need to be filled by data from the relevant studies or by application of the adaptation possibilities foreseen in the REACH Regulation. In this case, the Appellant sought to meet the information requirements by use of a read-across adaptation pursuant to Section 1.5 of Annex XI. As this approach was rejected by the Agency following an evaluation compliance check, the Agency had no option but to require the information set out in the relevant Annexes. The Agency was not therefore required to examine the proportionality of these information requirements as they are specified in the REACH Regulation itself.

119. The Board of Appeal finds therefore that the Appellant's claim with regard to the proportionality of the contested part of the Contested Decision must be rejected as unfounded.

Appellant's fifth plea regarding the illegality of the decision-making procedure

Arguments of the Parties

120. The Appellant submits that it was unable to attend the MSC meeting at which the Contested Decision was discussed. The Appellant adds that since it has a deep and thorough understanding of VEHA and the source substances its opinion on the proposed read-across should have been fully understood and taken into account at the relevant MSC meeting. In this respect the Appellant claims that its right to be heard had been breached.

121. The Appellant also claims that the Agency failed to properly safeguard its rights during the decision-making process and to put the Appellant in a position where it would have been able to attend the MSC meeting at which the Contested Decision was adopted.

122. The Agency stated in its Defence that the EU legislator did not envisage that a registrant could be present at MSC meetings; instead the legislator foresaw that procedural guarantees are provided to registrants throughout the entire decision-making process by application of Articles 50 and 51 of the REACH Regulation. The Agency states further that in addition to the actions described in those Articles, the Agency has on its own initiative offered registrants the possibility to informally discuss the scientific rationale behind draft decisions, for example in the form of teleconference, an opportunity which the Appellant did not take in this case. The Appellant was also invited to the MSC meeting but did not respond to the invitation. The Agency considers that the Appellant had been put in a position in which it could effectively make its views known.

123. The Agency stated further that during the decision-making procedure the MSC and the Agency executed their tasks in a legally sound manner, following the dossier evaluation process set out in Articles 50 and 51 of the REACH Regulation.

124. The Agency claimed further that because the invitation to the MSC meeting is within the MSC's discretion, there was no reason to check whether the invitation to the MSC meeting had been received correctly.

Findings of the Board of Appeal

125. For the purpose of this plea, the Board of Appeal will examine whether the Agency safeguarded the Appellant's procedural rights during the procedure leading to the adoption of the Contested Decision and placed the Appellant in a position in which it could effectively make known its views on the draft decisions of 29 April 2011 and 20 January 2012. This involves inter alia examining whether the failure to receive the invitation to the MSC meeting sent by the Agency on 14 March 2012 was due to a potential failure in the communication activities of the Agency. In addition, it is necessary for the Board of Appeal to consider whether the Agency acted in a legally correct manner when inviting the Appellant to the MSC meeting but not postponing the meeting in its absence.

126. On the basis of the evidence and arguments presented to the Board of Appeal in the various submissions and at the oral hearing, the Board of Appeal finds that the decision-making procedure foreseen in Articles 50 and 51 of the REACH Regulation in this case had been correctly followed. According to the evidence submitted, the draft decisions of 29 April 2011 and 20 January 2012 were correctly notified to the Appellant which was also provided a possibility to submit its comments as required in the REACH Regulation. The Board of Appeal considers that the comments provided by the Appellant as well as the update of the dossier made by the Appellant on 27 May 2011 were taken into account by the Agency during the decision-making procedure. In addition, the Board of Appeal notes that the Appellant did not make use of the possibility to discuss the draft decision at a telephone conference offered to it by the Agency.

127. The Board of Appeal also finds that the Agency is correct in its finding that the REACH Regulation does not foresee the participation of registrants at the MSC meeting and therefore, in principle, it is in the discretion of the MSC to decide whether such participation is appropriate. Consequently, the mere fact that in this case the Appellant did not participate at the meeting cannot as such cause a breach of due process.

128. The Appellant claims that the Agency did not put the Appellant in a position where it was able to participate at the MSC meeting as the Agency did not check that the Appellant had actually received the invitation to the meeting and proceeded with the decision-making process despite the absence of the Appellant. When analysing the actions by the Agency in this regard, the Board of Appeal notes that the invitation to the Appellant was sent through the Appellant's REACH-IT account which forms the key communication tool used between the Agency and registrants during the registration procedure. The Appellant stated during the proceedings, however, that its REACH-IT account was not monitored regularly due to a change in personnel. The invitation to the meeting of the MSC meeting was sent by the Agency in due time but was not in practice received in time by the Appellant due to the change in personnel and the fact that the contact information in its REACH-IT account had not been updated.

129. The Board of Appeal finds that every registrant has the duty to act in a diligent and prudent manner when fulfilling obligations pursuant to the REACH Regulation. At the same time, the Board of Appeal stresses that the registrant's duties do not discharge the Agency from its obligation to safeguard that during the decision-making procedure the registrant is put into position to both express its view as well as to safeguard its rights efficiently.

130. As the Board of Appeal has stated, it is the responsibility of every registrant to update the information concerning its user account details in REACH-IT (see Board of Appeal Decision of 27 February 2013 in Case A-005-2012, SEI EPC Italia SpA paragraph 34). The Board of Appeal finds that it is reasonable to expect that the Appellant should have understood the importance of keeping the contact information in the REACH-IT account up-to-date, particularly at the time when a dossier evaluation was on-going and a draft decision was pending. The Board of Appeal finds also that it is reasonable to expect that the Appellant understood that the MSC could adopt the final decision without the Appellant's presence at the meeting.

131. As a result, particularly also taking into account the fact that after receiving the invitation the Appellant still had the opportunity to participate but decided not to do so and nor did it contact the Agency to inform it about the late arrival of the invitation, it is clear that the reason for the Appellant's claimed inability to participate at the MSC meeting was not due to any procedural failure by Agency but the actions, and inactions, of the Appellant itself.

132. In view of the above, the Appellant's fifth plea, and therefore the appeal in its entirety, must be dismissed.

Other issues under examination

Refund of the appeal fee

133. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.

134. As the Board of Appeal has decided the appeal in favour of the Agency in the present case, the appeal fee shall not be refunded.

Effects of the Contested Decision

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

136. The part of the Contested Decision contested in the present proceedings, and upheld by the Board of Appeal, required the Appellant to submit the information set out in paragraph 21 above within 12 months of the date of the adoption of the Contested Decision, in other words by 21 June 2013. The Board of Appeal considers however 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) of the REACH Regulation, as if it referred to 12 months from the date of the final decision of the Board of Appeal.

137. Consequently, the Appellant shall submit the information required in the contested part of the Contested Decision within 12 months from the date of notification of the Board of Appeal's Decision in the present case.

ORDER

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the appeal fee shall not be refunded.**
3. **Decides that the Appellant shall submit information for VEHA on:**
   - **skin sensitisation (Section 8.3 of Annex VII; EU test method B.42.);**
   - **in vitro gene mutation in mammalian cells (Section 8.4.3 of Annex VIII; EU test method B.17); and**
   - **in vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Section 8.4.2 of Annex VIII; EU test method B.10 or draft OECD guideline 487)**

   as required by the parts of the Agency's Decision CCH-D-0000002304-84-04/F of 21 June 2012 contested in the present proceedings, within 12 months from the date of notification of the Board of Appeal's decision in this case.

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal