EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

19 June 2013

(Evaluation – Compliance check of a registration dossier – Request to submit further information – Rejection of proposed read-across approach – Agency's margin of discretion)

Case number	A-001-2012
Language of the case	English
Appellant	Dow Benelux B.V. Netherlands
Representative	Hartmut Scheidmann and Michael Winkelmüller Redeker Sellner Dahs - Rechtsanwälte Berlin Germany
Intervener	The European Coalition to End Animal Experiments United Kingdom Represented by: Katy Taylor London United Kingdom
Contested decision	CCH-D-0000001716-72-04/F of 24 October 2011 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 and Rapporteur), Andrew FASEY (Technically Qualified Member) and Rafael LÓPEZ PARADA (Legally Qualified Member)

Registrar: Sari HAUKKA

gives the following

Decision

RELEVANT LEGISLATION

The REACH Regulation

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

   '*1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. […]*'

   3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.'

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). […]'

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 (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;

   […]

   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 76(1)(e) of the REACH Regulation provides:

'The Agency shall comprise:
[…] a Member State Committee, which shall be responsible for resolving potential divergences of opinions on draft decisions proposed by the Agency or the Member States under Title VI.'

7. Article 130 of the REACH Regulation provides:

'*[…] the Agency […] shall state reasons for all decisions [it] take[s] under this Regulation.'*

8. Annex XI of the REACH Regulation on General rules for adaptation of the standard testing regime set out in Annexes VII to X provides, inter alia:

'*Annexes VII to X set out the information requirements for all substances manufactured or imported in quantities of:*

[…]

- 100 tonnes or more in accordance with Article 12(1)(d), […]

In addition to the specific rules set out in column 2 of Annexes VII to X, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of this Annex. Under dossier evaluation the Agency may assess these adaptations to the standard testing regime.

1. Testing does not appear scientifically necessary

[…]

1.2 Weight of evidence

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.

There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3) or from an international test method recognised by the Commission or the Agency as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

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,

— further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

[…]

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. 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

9. On 10 November 2008, the Appellant submitted a registration for the substance dipropylene glycol methyl ether acetate (hereinafter 'the Substance' or 'DPMA') at the tonnage level of 1 to 10 tonnes per year. On 8 September 2009, the Appellant updated the dossier to the tonnage level of 100 to 1 000 tonnes per year.

10. The registration dossier submitted by the Appellant contained adaptations to the standard testing regime through the use of a read-across approach from a supporting substance to the Substance for the endpoints on sub-chronic repeated dose toxicity (Section 8.6.2 of Annex IX to the REACH Regulation) and pre-natal developmental toxicity (Section 8.7.2 of Annex IX to the REACH Regulation). The dossier also contained the results of a repeated dose toxicity study and the results of two pre-natal developmental toxicity studies for dipropylene glycol methyl ether ('DPM') as a surrogate for the Substance. The Appellant proposed a read-across approach for the results of the studies on DPM to DPMA with the justification that the Substance is expected to rapidly hydrolyse to DPM. However, the Appellant did not provided toxicokinetic data for DPMA showing that such hydrolysis occurs.

11. On 21 June 2010, the Agency initiated a dossier compliance check of the Appellant's registration dossier for the Substance. Further to this, the Agency prepared a draft decision pursuant to Article 41(3) of the REACH Regulation by which its intention was to require the Appellant to submit, pursuant to Articles 41(1)(a), 41(1)(b), 41(3), 10(a)(vii), 12(1)(d) and 13, as well as Annexes VIII, IX and XI to the REACH Regulation information for the Substance using the following test methods, first, an *in vitro* gene

mutation on mammalian cells (hereinafter the 'mutagenicity study'), second, a 90-day sub-chronic repeated dose toxicity study in the rat, male and female, by the oral route (test method B.26 of Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1) or OECD 408 (hereinafter the 'RDT study') and, third, a pre-natal developmental toxicity study, in the rat, by the oral route (test method B.31 of Commission Regulation (EC) No 440/2008 or OECD 414) (hereinafter 'the Study').

12. In relation to the read-across proposed by the Appellant, the Agency concluded in its draft decision that the read-across from DPM to the Substance is not acceptable for the endpoints in question. The Agency's reasons, inter alia, state that the Substance contains an acetate functional group not present in DPM and therefore does not fulfil the criterion in Section 1.5(2) of Annex XI to the REACH Regulation and that there is no data to support the Appellant's hypothesis that the Substance undergoes rapid hydrolysis, so the criterion in Section 1.5(3) of Annex XI to the REACH Regulation is not met.

13. On 3 November 2010, the Agency notified the draft decision to the Appellant inviting it, pursuant to Article 50(1) of the REACH Regulation, to submit comments by 3 December 2010. The Agency also offered the Appellant an opportunity to discuss the scientific background to the draft decision with the Agency.

14. On 18 November 2010, the Agency and the Appellant held a teleconference to discuss the draft decision.

15. On 29 November 2010, the Appellant submitted comments on the draft decision, and subsequently, on 31 March 2011, submitted an update of the dossier containing the results of a toxicokinetics study, investigating the hydrolysis of the Substance *in vitro*.

16. On 17 June 2011, pursuant to Article 51(1) of the REACH Regulation, the Agency notified the draft decision to the competent authorities of the Member States (hereinafter the 'MSCAs') and invited them to propose amendments.

17. By 18 July 2011, the Agency had received comments and proposals for amendments from two MSCAs.

18. On 20 July 2011, the Agency notified the MSCAs' comments to the Appellant in accordance with Article 51(5) of the REACH Regulation, and invited the Appellant to provide comments on the proposed amendments.

19. On 1 August 2011, after considering the MSCAs' proposals for amendments, the Agency decided not to further amend the draft decision and referred it to the Member State Committee (hereinafter the 'MSC'), in accordance with Article 51(3) of the REACH Regulation.

20. On 16 August 2011, the Appellant submitted comments on the MSCAs' proposals for amendments.

21. From 20 to 23 September 2011, a meeting of the MSC took place at which the Agency's draft decision was discussed. The Appellant also participated at the meeting as the case owner and attended the initial discussions of the MSC on the Agency's draft decision. Following discussions in a closed session, the draft decision was modified. The Agency proposed not to request the 90-day sub-chronic repeated dose toxicity study but to maintain the request for the pre-natal developmental toxicity study. The MSC supported the Agency Secretariat's argumentation and agreed that the sub-chronic repeated dose toxicity study will not be required from the registrant in the draft decision and that the statement of reasons will be modified accordingly. The agreed modifications were made in the draft decision that was then referred to the MSC. On 23 September 2011, the MSC reached a unanimous agreement on the Agency's draft decision and adopted the formal agreement.

22. On 24 October 2011, the Agency adopted the Contested Decision and notified it to the Appellant. In the Contested Decision the Agency concluded that the registrant had not established a basis for showing that DPM can be read-across to the Substance for the

endpoint on pre-natal developmental toxicity and requested the Appellant to submit the information for the Substance by performing the Study. The Agency also requested the Appellant to submit missing information for the Substance by performing the mutagenicity study.

PROCEDURE BEFORE THE BOARD OF APPEAL

23. On 24 January 2012, the Appellant lodged a notice of appeal at the Registry of the Board of Appeal challenging the Contested Decision which obliged the Appellant to submit for the Substance information obtained by performing the mutagenicity study and the Study. The Appellant requested the Board of Appeal to annul the Contested Decision and order the refund of the appeal fee.

24. By letter received on 5 March 2012, the European Coalition to End Animal Experiments (hereinafter 'ECEAE') applied to intervene in the proceedings before the Board of Appeal in support of the Appellant.

25. On 7 March 2012, the application to intervene was notified to the Appellant and the Agency. Both parties submitted observations on the application. By a decision dated 26 April 2012, the Board of Appeal granted the application to intervene.

26. On 26 March 2012, the Agency submitted the defence. The Appellant was invited to submit observations on the Agency's defence.

27. On 30 April 2012, the Appellant lodged observations on the defence. In its observations, the Appellant also stated that it was withdrawing its claim related to the mutagenicity study.

28. By letter dated 13 April 2012, the Agency informed the Board of Appeal that, further to the Appellant's request in the notice of appeal, it had disclosed to the Appellant the official record of the decision-making procedure relevant to the present appeal proceedings. The letter was notified to the Appellant on 16 April 2012.

29. On 1 June 2012, ECEAE lodged observations on the notice of appeal and the defence. Both parties submitted observations on the interveners' observations.

30. On 27 July 2012, the Board of Appeal requested the Agency and the Appellant to provide certain information related to the Agency's decision-making process, to the extent that these had not been submitted previously in the proceedings. At the same time, the Agency was invited to submit observations on the Appellant's observations on the defence, and the Appellant was invited to submit observations on certain points raised by the Agency in its observations on the intervener's observations.

31. On 5 September 2012, the Appellant responded to the Board of Appeal's request of 27 July 2012 and submitted observations on the Agency's observations on ECEAE's observations.

32. On 12 September 2012, the Agency responded to the request of 27 July 2012 by submitting confidential and non-confidential versions of the documents it considered to be the official record of the decision-making process that lead to the adoption of the Contested Decision. The Agency submitted copies of correspondence between the Agency and the Appellant, as well as copies of documents and communications exchanged between the Agency, the MSCAs and the MSC during the decision-making process. On the same day, the Agency also submitted observations on the Appellant's observations on the defence. The Agency's observations contained a request to treat certain information as confidential. More specifically, the Agency requested that certain personal data, information related to the registered substance, documents submitted by the Appellant during the decision-making process, and parts of MSC documents unrelated to the present case should not be disclosed to third parties.

33. On 8 October 2012, the parties and the intervener were notified of the Board of Appeal's decision to close the written procedure.

34. On 18 October 2012, the Agency informed the Board of Appeal that it did not request a hearing to be held. On the same date, the Appellant requested a hearing to be held.

35. On 23 October 2012, since a member of the Board of Appeal was precluded from participating in the proceedings, the Chairman, pursuant to the first subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 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') designated an alternate member, Rafael López Parada, to act in the present case as the legally qualified member of the Board of Appeal.

36. In accordance with Article 13 of the Rules of Procedure, following the request of the Appellant for a hearing to be held, the parties were summoned to a hearing which was held on 12 February 2013. The intervener was also invited to participate in the hearing. Oral presentations were made by the parties and the intervener. The members of the Board of Appeal also posed questions to the parties and the intervener.

ARGUMENTS OF THE PARTIES

Appellant's arguments

37. In the notice of appeal the Appellant challenged the Contested Decision's requirements to submit additional information related to the performance of the Study and the mutagenicity study. As mentioned in paragraph 27 above, the Appellant later withdrew its claim related to the mutagenicity study.

38. The Appellant supported its claim related to the performance of the Study with the following pleas of law and fact:

    (i) The Contested Decision is illegal as the Agency's dossier evaluation procedure is not compliant with the requirements of the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU; both published in OJ C 326 of 26.10.2012; Consolidated version 2012).

    (ii) The Contested Decision infringes formal legal requirements for decision-making and is illegal. The Appellant's right to be heard has been violated and, by adopting the Contested Decision, the Agency failed in its obligation to give an appropriate statement of reasons.

    (iii) Finally, the Contested Decision is unlawful because the Agency has, firstly, unlawfully rejected a scientifically justified read-across approach to generate information required for registration purposes and, secondly, misused its margin of discretion by rejecting the Appellant's justification for the read-across and by requiring the Appellant to conduct the Study.

39. The Appellant's arguments can be further summarised as follows:

    (a) The wide margin of discretion granted to the Agency in the framework of the dossier evaluation decision-making provisions, namely Articles 41(3), 50 and 51 of the REACH Regulation, as regards the request for further information is unlawful as it is incompatible with the principle of institutional balance established under European Union law. Such transfer of decision-making powers of a discretionary nature constitutes an inadmissible transfer of responsibility from the Commission to an institution (i.e. the Agency) not governed by the European Treaties.

    (b) The MSC exceeded the limits of its powers with the discretionary decision taken on 23 September 2011. According to Article 51(6) of the REACH Regulation, read in conjunction with Article 291(2) and (3) TFEU and Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13;

hereinafter the 'Comitology Regulation'), the MSC has only limited powers to make its own decisions. The Contested Decision is illegal, as there is no legal basis allowing the MSC to modify the Agency's draft decision and subsequently come to a unanimous agreement on it. The MSC should have only been able to consent to the draft decision of the Agency or reject it.

(c) The Appellant argues that the right to be heard is one of the fundamental principles of Union law, which the European Union and its bodies need to respect. Furthermore, that right is provided for in Article 41(2)(a) of the Charter of Fundamental Rights of the European Union (OJ 2010 C 83, 30.3.2010, p. 389; hereinafter the 'Charter'). The Contested Decision deviates substantially from the draft decision submitted to the MSC on 1 August 2011 and the draft decision on which the MSCAs made proposals for amendment and on which the Appellant had the opportunity to comment. No further hearing has been accorded to the Appellant to comment on the version of the draft decision as amended at the MSC meeting on 23 September 2011. The Agency did not consider the extensive scientific arguments submitted by the Appellant. Furthermore, the Contested Decision is 'Überraschungsentscheidung' (a surprising decision), which has been taken without any announcement, spontaneously in the closed session of the MSC meeting and without any involvement of the Appellant.

(d) The Contested Decision does not fulfil the Agency's obligation to give an appropriate statement of reasons, which is provided in Article 130 of the REACH Regulation and in primary European Union law. First, the Contested Decision only repeats the grounds of the draft decision concluding that the read-across approach does not apply generally whilst in the Contested Decision the read-across approach is only specifically denied for the pre-natal developmental toxicity study yet accepted for the sub-chronic repeated dose toxicity endpoint. The Agency does not provide any reasons for this difference in approach between endpoints. Second, the Appellant's profound and substantial scientific argumentation, in particular in its response to the Agency and the MSC of 16 August 2011, is not reflected in the reasoning. Third, the fact that the read-across approach proposed by the Appellant has already been accepted by the Organisation for Economic Co-operation and Development (hereinafter the 'OECD'), cannot be ignored by the Agency in its final decision. Fourth, considering the consistency and validity of the Appellant's argumentation, the Agency was obliged to explicitly point out in which respect and by virtue of which scientific considerations it fails to be convinced by the arguments for the read-across. Finally, in the light of the foregoing arguments, the Appellant cannot understand the factual reasons upon which the Agency based the Contested Decision. Specifically, the Agency failed to explain what rate of hydrolysis would have been considered to be sufficiently rapid and what additional evidence would be necessary to justify the read-across approach.

(e) Regarding the alleged material illegality of the Contested Decision, the Appellant's arguments are twofold.

First, the Appellant contends that the Agency unlawfully, without sufficient justification, rejected a scientifically justified read-across approach. This is in particular based on the Appellant's scientific conclusions that the Substance manifests a non-hazardous, harmless toxicity profile similar to DPM, propylene glycol methyl ether ('PM') and propylene glycol methyl ether acetate ('PMA'). Moreover, the Substance will rapidly hydrolyse *in vivo* to DPM. In that regard the Appellant also refers to a Physiologically Based Pharmacokinetic Model (hereinafter the 'PBPK model') to further substantiate its read-across approach to generate information required for registration purposes.

Second, by obliging the Appellant to perform further studies, the Agency misused its margin of discretion by rejecting a justified read-across proposal. Moreover, due to the consistency and validity of the Appellant's argumentation, the OECD's acceptance of the read-across approach, the insignificance of remaining doubts

related to toxicity of the Substance before hydrolysis, its rapid hydrolysis *in vivo*, and the exceptional importance of animal welfare, the discretion of the Agency was reduced to zero, thus making illegal any decision contrary to the acceptance of the read-across approach for the pre-natal developmental toxicity endpoint.

Finally, the Contested Decision was taken in order to achieve a political compromise in the MSC. Instead of profound scientific reflection, the Agency opted for a fast but inconsistent and insufficient decision, demonstrating an insufficient handling of the read-across approach in general, apparently due to ignorance of how to deal with the issue.

Agency's defence

40. The Agency's arguments related to the Appellant's claim concerning the performance of the Study can be summarised as follows:

(i) The Board of Appeal should determine whether it is competent to address the Appellant's claim that decision-making powers with a margin of discretion should not be conferred on European Union bodies such as agencies, thereby questioning the legality of the legislator's decision to confer on the Agency the competence to issue individual decisions following dossier evaluations.

(ii) Article 76(1)(e) of the REACH Regulation provides for an explicit legal basis for the MSC to modify a draft decision of the Agency in order to resolve any divergences of opinion between the elements requested in the referred draft decision, the proposals for amendment submitted by MSCAs and the comments received from the Appellant on the proposals for amendment.

(iii) The Agency fully respected the procedure for decision-making, in which the REACH Regulation institutionalised the right to be heard for addressees of evaluation decisions. The Agency consulted the Appellant at several steps in the procedure. The Appellant was, in accordance with Article 50(1) and (5) of the REACH Regulation, invited to comment on the initial draft decision and on the proposals for amendments made by the MSCAs. In addition, the Appellant was granted the opportunity to update its dossier prior to submission of the draft decision to the MSCAs and, later, it was invited to participate as a case owner in the MSC meeting where it could articulate its views. The possibility for the case owner to participate in the MSC meeting represents an additional step not foreseen in the REACH Regulation and was introduced by the Agency for transparency reasons. Furthermore, a final decision may deviate from the opinion of its addressee whilst complying entirely with the principle of the right to be heard. In addition, the Contested Decision did not contain any elements that were not in the draft decision discussed during the decision-making procedure. Moreover, the Contested Decision is less onerous for the Appellant. As the Agency decided not to require information on sub-chronic repeated dose toxicity endpoint, the Contested Decision contains fewer obligations than the draft decisions.

(iv) The Agency considers that the Contested Decision gives appropriate reasons for requiring the Study and rejecting the read-across approach. Also, the Agency's reasoning contained in its initial draft decision remained valid until the end of the decision-making procedure and the adoption of the final decision. Furthermore, it is not for the Agency to justify in its decision the non-inclusion of elements that were included in the draft decision. Regarding the removal of a request to perform a 90-day repeated dose toxicity study from the Contested Decision, the explanation for this was provided to the Appellant in the minutes of the MSC meeting.

(v) In the Contested Decision, the Agency has considered that the conditions for a read-across adaptation, i.e. the omission of test data for pre-natal developmental toxicity in the case at hand by way of read-across to an analogue substance DPM, are not met as the Appellant could not demonstrate that the requirements of

Section 1.5 of Annex XI to the REACH Regulation were met. This has been the position of the Agency throughout the process that lead to the adoption of the Contested Decision and there is no other information available that would lead to a different conclusion. Consequently, the Agency was justified in rejecting the proposed read-across and in requiring the Study.

(vi) Pursuant to Article 41 of the REACH Regulation, the Agency is competent to assess the compliance of registration dossiers vis-à-vis the requirements of the REACH Regulation. In that context, no limitation to this discretion can be derived from assessments carried out by international organisations such as the OECD. A read-across from the OECD high production volume ('HPV') chemicals programme cannot be automatically accepted as meeting the REACH information requirements, in part, because the objectives of the two programmes may differ. The assessment of the OECD also contains the prerequisite for rapid hydrolysis that the Agency assessed quantitatively and as a key issue in the acceptance or otherwise of the read-across argument. Moreover, the Agency contends that the pre-natal developmental toxicity study is not an OECD Screening Information Dataset's endpoint. Finally, REACH is underpinned by the precautionary principle set out in Article 1(3) of the REACH Regulation. The principle gives competence and discretion to regulators to request further data in case of doubt, namely experimental data in the context of dossier evaluation in order to achieve the objective of the legislation for a high level of protection.

Intervener's arguments

41. The arguments presented by ECEAE can be summarised as follows:

(i) The Agency erred in law by focusing on the bioavailability of the Substance for a short period during hydrolysis and fails to consider the more fundamental question of whether the Substance and DPM are sufficiently structurally similar to enable read-across, which would render largely irrelevant the bioavailability question. The MSC and/or the Agency did not properly address the question of whether there is sufficient similarity to predict the toxicological properties identified in the first subparagraph of Section 1.5 of Annex XI to the REACH Regulation and thereby enabling classification and labelling and risk assessment. Considering the key role of read-across to avoid unnecessary animal tests and its inherent lack of certainty, the Agency should not set the structural comparison bar too high.

(ii) The Agency has failed to take into account or give appropriate weight to the fact that the OECD HPV chemicals programme accepts the read-across approach set-out in the registration dossier even without definitive hydrolysis data.

(iii) Animal welfare is a key objective of REACH and as such is relevant to the approach the Agency should have taken in the present case. The Agency is wrong in saying that it cannot take into account animal welfare in its decision-making. The Agency's view of its animal welfare remit is overly narrow and unlawful. In fact, the Agency does have a key role in ensuring that animal welfare is appropriately taken into account, i.e. it must ensure that the last resort principle in Article 25 of the REACH Regulation is fully respected in its evaluation decisions.

REASONS

I. Admissibility

42. The Board of Appeal will firstly examine the inadmissibility pleas that have been raised by the Agency during the proceedings.

1. Admissibility of evidence submitted by the Appellant outside the decision-making procedure leading to the adoption of the Contested Decision

43. In its defence, the Agency claimed that the results of the PBPK model which the Appellant submitted in its notice of appeal, should not be taken into account since the results were brought forward only in the context of the appeal proceedings. The Appellant, relying on Article 12(1) of the Rules of Procedure, argued that the Board of Appeal should take into account the PBPK model.

44. 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 a new plea is duly justified or based on new matters of law or fact that come to the light in the course of the proceedings.

45. The Board of Appeal observes that the Agency's objection to accepting the PBPK model as evidence is not based on the limitation provided in the Rules of Procedure but on the reasoning that it constitutes new information which was not brought forward during the decision-making procedure but only later in the context of the appeal proceedings.

46. 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.

47. The Board of Appeal observes, first, and as also pointed out by the Agency, that the Appellant did not make available to the Agency the information from the PBPK model during the decision-making process leading to the adoption of the Contested Decision.

48. Second, the Board of Appeal observes that the Appellant presented the PBPK model to explore further the rate of hydrolysis of DPMA to DPM *in vivo*. During the decision-making process the Appellant explored the issue by providing the information on the *in vitro* toxicokinetic study of the hydrolysis of DPMA to DPM. Consequently, the Board of Appeal considers that the introduction of the PBPK model as evidence was intended to supplement the results of the *in vitro* toxicokinetic study, and support the contention regarding rapid hydrolysis of the Substance to DPM already presented during the decision-making process.

49. For the above reasons, the Board of Appeal therefore finds that the PBPK study, which was submitted by the Appellant in its notice of appeal, is admissible in the present proceedings.

50. In its submissions of 12 September 2012, the Agency also claimed, in relation to the information on toxicological properties of the propylene glycol ethers (hereinafter 'P-series glycol ethers') that, when commenting on proposals for amendments to the draft of the Contested Decision, the Appellant had not provided any arguments to justify why information from other substances of the P-series glycol ethers can be used for predicting the pre-natal developmental toxicity of the Substance. The Agency consequently argues that the Appellant's reference, in its observations on the Agency's defence, to the toxicology of other substances of the P-series glycol ethers to predict the toxicity of the Substance, constitutes new information that has not been submitted during the decision-making process and should not therefore be taken into account when assessing the legality of the Contested Decision.

51. The Board of Appeal observes that, in its comments on the draft decision of 29 November 2010, when making a reference to the toxicological properties of the P-series glycol ethers, the Appellant stated that the glycol ethers under discussion in the OECD-SIDS programme and also the former EU Existing Chemicals programme include PM, PMA, DPM and DPMA, i.e. 'P'-series glycol ethers, including the Substance.

52. For the above reasons, the Board of Appeal considers that, in its comments on the draft decision of 29 November 2010, the Appellant mentioned the Substance as one of the substances subsequently discussed in the paper on toxicological properties of P-series

glycol ethers. Consequently, the Board of Appeal finds that the Appellant's reference to the toxicology of other P-series glycol ethers to predict the toxicity of the Substance, as submitted by the Appellant in its comments on the Agency's defence, is admissible in the present proceedings.

53. The Board of Appeal therefore dismisses the Agency's claims of inadmissibility of evidence related to the PBPK model and the paper on toxicology of other P-series glycol ethers to predict the toxicity of the Substance.

II. Claims under examination

1. Complaint alleging unlawful assignment of decision-making powers to the Agency

54. The Appellant submits, in essence, that the Agency's decision-making powers in the framework of dossier evaluation under the REACH Regulation, in particular Articles 41(3), 50 and 51 thereof, constitute a breach of the principle of institutional balance as it is known in European Union law and that, consequently, the Contested Decision is illegal.

55. The Agency considers that the Board of Appeal is not competent to address the Appellant's plea, which is in any event unfounded.

56. The Board of Appeal observes at the outset that the Contested Decision was taken by the Agency pursuant to Article 41(3) of the REACH Regulation and in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation. Since those rules, governing the compliance check of registrations and the procedure for adoption of decisions under dossier evaluation, have not been found to be unlawful and were therefore fully effective at the time of the adoption of the Contested Decision, the Agency was under a duty to apply them. If it had not done so, the Agency would have disregarded the presumption of legality.

57. Consequently, the Board of Appeal is of the opinion that the adoption of the Contested Decision by the Agency pursuant to Article 41(3) of the REACH Regulation and in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation cannot be called into question.

58. In that regard, it must be stated that by questioning the legality of Articles 41(3), 50 and 51 of the REACH Regulation, the Appellant is in principle raising a plea of illegality. It is however not for the Board of Appeal to rule on the legality of the provisions of the REACH Regulation. That is a power which lies exclusively with the Court of Justice of the European Union (see in this regard the Decision of the Board of Appeal of 7 October 2011 in case A-004-2011, paragraph 66).

59. It follows from the above that the Appellant's complaint alleging unlawful assignment of decision-making powers to the Agency must be dismissed as inadmissible.

2. Complaint alleging that the MSC exceeded its decision-making competences

60. The Appellant submits, in essence, that the MSC exceeded the limits of its powers when it reached unanimous agreement on the Agency's draft decision that lead to the subsequent adoption of the Contested Decision. The Appellant claims that as there is no legal basis allowing the MSC to modify the Agency's draft decision and subsequently come to a unanimous agreement on it, the Contested Decision is illegal.

61. The Agency disputes that claim.

62. The Board of Appeal shall consider whether the Agency's actions related to the dossier evaluation in the present case complied with the provisions of the REACH Regulation which provides the legal framework for dossier evaluation. Accordingly, the Board of Appeal shall examine whether, in the present case, the MSC and consequently the

Agency acted outside of the legal framework provided by the REACH Regulation, in particular Articles 51 and 76(1)(e) thereof.

63. The Appellant, in principle, disputes the Agency's interpretation of Article 76(1)(e) of the REACH Regulation which provides that the MSC shall be, inter alia, responsible for resolving potential divergences of opinions on draft decisions proposed by the Agency or the Member States.

64. In that regard, it is apparent from the provision of Article 76(1)(e) of the REACH Regulation that seeking a resolution of potential divergences of opinions by the MSC entails coming to an agreement on the draft decision taking into account all the related information. The information consists of the draft decision prepared by the Agency, the comments of the registrant (i.e. the Appellant in the present case), proposed amendments of the MSCAs to the draft decision, and the registrant's comments on them. The Board of Appeal considers that if the MSC's competences were limited to either agreeing or disagreeing with the draft decision of the Agency, as argued by the Appellant, the MSC could not contribute to the decision-making in dossier evaluation in a meaningful manner. Such an interpretation of Article 76(1)(e) would defeat its purpose which calls for the significant involvement of the MSC with regard to the adoption of decisions under dossier evaluation.

65. Moreover, the procedural steps provided for in Article 51 of the REACH Regulation presuppose that the MSC has a certain amount of discretion when performing its tasks under the REACH Regulation, which relate to seeking a common scientific and regulatory understanding of all Member States with regard to dossier evaluation decisions.

66. In addition, as the Agency argues, the Appellant's interpretation of Article 76(1)(e) of the REACH Regulation runs counter to the objective of the REACH Regulation which aims to reduce the number of decisions taken at the European Commission level by conferring on the Agency, including its MSC, decision-making powers.

67. The Board of Appeal is of the opinion that the above conclusions cannot be called into question by the Appellant's claim that the involvement of the MSC in the dossier evaluation decision-making process should be considered in the context of European primary law and the Comitology Regulation.

68. In that regard, the Board of Appeal considers that the Appellant is not justified in drawing parallels between the dossier evaluation decision-making process under the REACH Regulation and the procedures that are designed for decision-making in the comitology procedures at the Commission.

69. The Board of Appeal considers that the legislative framework of the REACH Regulation and, in particular Articles 51 and 76(1)(e) thereof, allowed the MSC, in the circumstances of the present case, to reach unanimous agreement on the Agency's draft decision that lead to the subsequent adoption of the Contested Decision.

70. It follows from the above that the Appellant's complaint alleging that the MSC exceeded its decision-making competences must be dismissed as unfounded.

3. Complaint alleging the violation of the Appellant's right to be heard

71. In accordance with settled case-law of the Court of Justice of the European Union, observance of the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question (Case C-32/95 P *Commission* v *Lisrestal and Others*, [1996] ECR I-5373, paragraph 21; see also Article 41(2) of the Charter). That principle requires that the addressee of a decision which significantly affects its interests should be given the opportunity to effectively make known its views on the correctness and relevance of the facts, objections and circumstances put forward

by the institution (see e.g. Case T-314/01 *Avebe* v *Commission*, [2006] ECR II-3085, paragraph 49 and the case-law cited therein).

72. Accordingly, it is necessary to consider whether the Agency placed the Appellant in a position in which it could effectively make known its views on the draft decisions of the Agency that lead to the adoption of the Contested Decision.

73. In that regard, the Appellant does not dispute that the Agency provided it, pursuant to Articles 50(1) and 51(5) of the REACH Regulation, with two opportunities to comment on the draft decisions. In fact, the Appellant used both of those opportunities to submit its comments.

74. The Appellant rather contests that, in its Contested Decision, the Agency deviated substantially from the previous drafts with no further opportunity to comment being accorded to the Appellant. In addition, the Appellant contends that the Agency did not consider the extensive scientific arguments that it submitted. Furthermore, the Appellant claims that the Contested Decision came as a surprise to it, as it was taken without any announcement, spontaneously, in the closed session of the MSC meeting and without any involvement of the Appellant.

75. The Agency submits that it did not breach the Appellant's right to be heard which was respected at all stages of the decision-making process.

76. The Board of Appeal considers that the Appellant is not justified in claiming that the Contested Decision deviates substantially from the previous draft versions. In that regard, the Contested Decision requires the Appellant to submit less information than was initially proposed in the draft decisions of 3 November 2010 and 17 June 2011. While those draft decisions required the Appellant to submit information regarding both the RDT study and the Study the Contested Decision only required that the Appellant submits information regarding the Study.

77. Moreover, when commenting on the draft decisions on 29 November 2010 and 16 August 2011, the Appellant submitted its comments in relation to both studies required by the Agency in its draft decisions. Consequently, the Board of Appeal does not accept the Appellant's view that the Contested Decision constitutes a 'surprise decision' taken by the Agency without any announcement.

78. Finally, the Appellant's argument that the Agency adopted the Contested Decision without any involvement of the Appellant cannot be accepted either. In that regard, the Board of Appeal notes that the right to be heard extends to all the factual and legal material which forms the basis of the decision, but not to the final position which the authority intends to adopt (see, for example Case T-16/02 *Audi* v *OHIM(TDI)*, [2003] ECR II-5167, paragraph 75 and, to that effect, Joined Cases T-129/95, T-2/96 and T-97/96 *Neue Maxhütte Stahlwerke and Lech-Stahlwerke* v *Commission*, [1999] ECR II-17, paragraph 231).

79. As explained in paragraph 77 above, the Appellant submitted comments in relation to the initial and revised draft decisions. The Board of Appeal therefore considers that the draft decisions of the Agency did enable the Appellant to identify, before the adoption of the Contested Decision, the facts and reasons taken into consideration by the Agency.

80. Consequently, the Board of Appeal concludes that the Agency based the Contested Decision on facts and reasons that were communicated to the Appellant prior to its adoption and that the Appellant submitted its comments on those facts and reasons.

81. It follows from the foregoing that the complaint alleging infringement of the Appellant's right to be heard must therefore be rejected.

4. Complaint alleging infringement of the obligation to state reasons

82. The Appellant submits, in essence, that it is not apparent on which factual reasons the Agency based the Contested Decision. The Appellant considers that in view of its

profound and substantial scientific argumentation in relation to the proposed read-across the Agency's reasoning is insufficient.

83. The Appellant also submits that the Agency provides no explanation, in the Contested Decision, as to why the proposed read-across approach is denied for the endpoint of pre-natal developmental toxicity while it was accepted with regard to the repeated dose toxicity endpoint.

84. In addition the Appellant claims that the Agency violated its duty to provide reasoning by ignoring the fact that the OECD's SIDS Initial Assessment Report on Propylene Glycol Ethers accepted the read-across approach.

85. The Agency disputes these claims and argues that the Contested Decision gives appropriate reasons for rejecting the proposed read-across approach and requiring the Study.

86. According to Article 130 of the REACH Regulation, the Agency shall state reasons for all decisions it takes under the Regulation.

87. That requirement has the same effect as that imposed by the second paragraph of Article 296 TFEU. Therefore the case-law of the Court of Justice of the European Union dealing with the requirement to state reasons provides a reference to the Board of Appeal when examining whether, in the present case, the Agency fulfilled its duty to provide reasons.

88. According to the settled case-law the statement of reasons required by Article 253 of the Treaty establishing the European Community (hereinafter the 'EC Treaty'; now Article 296 TFEU) must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the Court to exercise its power of review. The requirement to state reasons must be assessed according to the circumstances of the case. It is not necessary for the reasoning to go into all the relevant facts and points of law since the question of whether the statement of reasons meets the requirements of Article 253 of the EC Treaty must be assessed with regard not only to its wording but also to its context and all the legal rules governing the matter in question. In particular, the administration is not obliged to adopt a position on all the arguments relied on before it by the parties concerned; rather, it is sufficient if it sets out the facts and the legal considerations having decisive importance in the context of the decision (see for example Case T-445/05 *Associazione italiana del risparmio gestito and Fineco Asset Management* v *Commission*, [2009] ECR II-289, paragraph 66). In addition, the obligation to state reasons is a question separate from that of the merits of those reasons.

89. According to the Contested Decision, on the basis of information contained in the dossier and information submitted by the Appellant during the compliance check, the proposed read-across of information from DPM to DPMA is not acceptable. The Agency considered in the Contested Decision, first, that it had concerns over whether the hydrolysis of DPMA is sufficiently rapid to ensure that there is no systemic availability of the Substance and, second, that the pre-natal developmental toxicity of DPMA is not addressed by the available information on DPM, and that it is not possible to conclude that the DPMA would be unable to exert a toxic effect in the time that it is available in the body. In addition, the Agency stated that the Substance contains an acetate functional group that is not present in DPM which may impact on the toxicity of the Substance. As a consequence, the Contested Decision concluded that it is not possible to conclude that the requirements of Section 1.5 of Annex XI to the REACH Regulation governing grouping of substances and read-across approach are met.

90. Consequently, the Board of Appeal shall, having regard to the case-law mentioned in paragraph 88 above, examine whether the wording of the Contested Decision and its statement of reasons permitted the Appellant to determine the reasons for the decision.

91. The Board of Appeal considers that the Contested Decision sets out the decisive reasons, namely the speed of hydrolysis and presence of an acetate functional group in the Substance, which led the Agency to the conclusion that the read-across approach proposed by the Appellant to fulfil the information requirement cannot be accepted.

92. Furthermore, the statement of reasons in the Contested Decision makes it possible to understand why the Agency concluded that the read-across for the Substance as proposed by the Appellant cannot be accepted for the endpoint on pre-natal developmental toxicity.

93. The Board of Appeal also considers that the statement of reasons for the Contested Decision was sufficient to allow the Board of Appeal to review the decision and to deal with the various claims which have been put forward by the Appellant in its appeal. This finding cannot be called into question by the arguments that the Appellant put forward in support of its complaint.

94. First, the Appellant is not justified in claiming that no reasoning is provided in the Contested Decision as to why the read-across approach is denied only for the endpoint on pre-natal developmental toxicity. The Board of Appeal considers that the Agency's duty to provide reasons extends only to a measure contained in a contested decision and adversely affecting its addressee. The Agency cannot thus be obliged to provide reasons for why certain measures are not included in the decision. In the present case, the Contested Decision does not contain the requirement for the Appellant to submit information with regard to the sub-chronic repeated dose toxicity endpoint previously contained in the draft decision and 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 sub-chronic repeated dose toxicity endpoint. Similarly, the Agency was not under a duty to justify why the read-across approach was denied only for the pre-natal developmental toxicity endpoint. The Board of Appeal notes that the minutes of the MSC meeting of 20 to 23 September 2011 explain why it was decided not to request a repeated dose toxicity study from the Appellant.

95. Second, the Appellant is not justified in claiming that the Agency did not consider the scientific arguments that the Appellant provided in its comments of 16 August 2011 on the Agency's draft decision and on the comments of MSCAs as set out in the Summary of comments of the Registrant and proposals for amendment/comments of MSCAs related to ECHA's draft decision on a compliance check, and ECHA secretariat's responses to them of 19 August 2011 (hereinafter the 'RCOM'). In relation to the Appellant's comments of 16 August 2011 as regards the pre-natal developmental toxicity study, the Agency's secretariat mentioned in the RCOM that it cannot exclude the possibility that the Substance will exhibit effects not observed in other P-glycol ethers and that the proposed read-across does not address the toxicity of the Substance prior to hydrolysis. In addition, as mentioned in the RCOM, the toxicokinetic data suggests that the Substance will be available in the body for significant periods of time and that the Agency believes that a pre-natal developmental toxicity study is therefore necessary to address the potential adverse effects of the Substance. These considerations are also addressed in the reasons of the Contested Decision.

96. Third, it is necessary to examine the Appellant's claim that the Agency failed to take into account in the Contested Decision the fact that the read-across approach, rejected by the Agency in the proceedings leading to the adoption of the Contested Decision, has been entirely accepted in the OECD's SIDS report on Propylene Glycol Ethers. In this regard it is sufficient to note that the Appellant's claim is based on the premise that OECD's SIDS Initial Assessment Report on Propylene Glycol Ethers accepted the read-across approach suggested by the Appellant. The Agency emphasised, however, in its written submissions that, first, the OECD's assessment contained a prerequisite of rapid hydrolysis. Concerning the hydrolysis the Agency stated in the Contested Decision that the hydrolysis of DPMA is not sufficiently rapid to ensure that there is no systemic availability of the Substance. Second, the developmental toxicity addressed in the OECD's SIDS report is, in essence, a screening programme to help establish whether

further testing should be requested for a substance or group of substances and to assist in prioritisation of such testing. In relation to the Substance, the OECD's SIDS report on Propylene Glycol Ethers concludes that *'all category members but DPMA have been tested by various routes of exposure and in various species at significant exposure levels and show no frank developmental effects. Due to the rapid hydrolysis of DPMA to DPM, DPMA would not be expected to show teratogenic effects'*. The Board of Appeal finds that where the Agency considered that the hydrolysis of the Substance is not sufficiently rapid to ensure that there is no systemic availability of the Substance, it was not necessary for the Agency to further reason its decision not to accept the conclusions in the OECD's SIDS report on Propylene Glycol Ethers.

97. Fourth, in the Contested Decision the Agency explained why it considered that the Appellant's read-across approach does not meet the requirements of Section 1.5 of Annex XI to the REACH Regulation. It based its conclusion on the fact that, first, the hydrolysis of the Substance is not sufficiently rapid to ensure that there is no systemic availability of this substance and second that the pre-natal developmental toxicity of the Substance is not addressed by the available information on DPM. The Agency thirdly considered that the acetate functional group present in the Substance, but not in the source substance(s), may impact on its toxicity and that it is, due to the insufficiently rapid hydrolysis of the Substance, of relevance to the read-across. Consequently, the Appellant is not justified in claiming that the Agency failed to point out why it was not convinced by the Appellant's arguments.

98. Fifth, as mentioned in the previous paragraph, the Agency gave its reasons for concluding that the Appellant's read-across approach in the case at hand does not meet the requirements of Section 1.5 of Annex XI to the REACH Regulation. The Appellant cannot claim that the Agency had to explain what rate of hydrolysis would be sufficiently rapid or what additional evidence would be necessary in order to justify an acceptable read-across. In that regard, considering the provision of Article 1(3) of the REACH Regulation and the circumstances of the present case, it was for the Appellant to generate data to establish that its read-across approach fulfils the conditions of Annex XI for adaptations of the standard testing regime.

99. It follows from the foregoing that the complaint alleging infringement of the obligation to state reasons is unfounded.

100. The Board of Appeal observes that in order for a read-across approach to be accepted the criteria in Section 1.5 of Annex XI to the REACH Regulation have to be met and a registrant needs to present the information showing that these criteria have been met. In other words, the justification presented in a registration dossier may be exhaustive but if the adequacy of the read-across itself is not justified this is to no effect. The Appellant's complaint alleging material illegality of the Contested Decision will be examined next.

5. Complaint alleging the material illegality of the Contested Decision

101. The Appellant's complaint regarding the material illegality of the Contested Decision is twofold. The Appellant claims, in essence, that, first, the Agency unlawfully, without sufficient arguments, rejected a scientifically justified read-across proposal. Second, the Appellant, in essence contends that, by rejecting a justified read-across proposal and by obliging the Appellant to perform further studies, the Agency misused its margin of discretion.

102. Before examining the Appellant's complaint, it is appropriate to set out certain general considerations that are related to the arguments put forward by the Appellant and that will be taken into account by the Board of Appeal in determining whether the complaint is well founded.

103. The Board of Appeal 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 hazards 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, 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 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).

104. In addition, Article 41(1)(b) of the REACH Regulation provides that '[*t*]*he Agency may examine any registration in order to verify […] that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptions*'. Also, Article 41(3) of the REACH Regulation provides that '*[...] the Agency may […] prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements*'.

105. Bearing in mind the above considerations the Board of Appeal will examine the merits of the Appellant's complaint alleging material illegality of the Contested Decision.

106. The Contested Decision requires the Appellant, inter alia, to generate further information on the Substance in order to fulfil the information requirement related to pre-natal developmental toxicity (Section 8.7.2 of Annex IX to the REACH Regulation). The Appellant had sought an adaptation to the standard testing requirement by proposing to provide the required information by relying on a read-across approach. The Agency did not however accept the proposed read-across as it considered that it does not meet the requirements of Section 1.5 of Annex XI to the REACH Regulation.

107. In accordance with Article 13(1) of the REACH Regulation, a registrant may, when generating the required data on a substance that is being registered, generate information on intrinsic properties of the substance 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 from structurally related substances (grouping or read-across). When a registrant proposes adaptations to the standard information requirements, it shall, in accordance with Annex IX to the REACH Regulation, '[c]*learly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI'*.

108. The present case relates to the dossier evaluation procedure, in the context of a dossier compliance check. In this regard, it follows from the previous paragraphs that the Agency is responsible for assessing the acceptability of adaptations to the standard testing regime proposed by a registrant. In that context, for the Agency to be able to effectively pursue the objectives of the REACH Regulation, account being taken of the complex technical assessments which it must undertake, the Agency must be recognised as enjoying a broad discretion. This discretion is circumscribed by the relevant provisions of the REACH Regulation and its Annexes mentioned above.

109. The Board of Appeal considers that in the present case, in the context of the compliance check of the registration dossier, the Agency enjoyed a broad discretion. In particular, in order to determine the nature and scope of the measures which the Agency adopted, its examination of a proposal for adaptation of the standard information requirement entailed the assessment of complex scientific and technical facts. Consequently, the Board of Appeal shall consider whether, in the circumstances of the present case, by adopting the Contested Decision, the Agency misused its margin of discretion.

110. The Agency's discretionary powers have also been recognised by the Court of Justice of the European Union which has held that '[…] the Agency has a broad discretion in a

sphere which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments' (see Case C-15/10 *Etimine SA*, judgment of 21 July 2011, not yet reported, paragraph 125).

111. The Board of Appeal notes further that Annex XI of the REACH Regulation, which provides that '[t]he Agency *may* assess these adaptations to the standard testing regime' confers a wide margin of discretion on the Agency in the context of a dossier compliance check. In the same vein and more specifically, as regards the grouping of substances and read-across approach present in this case, Section 1.5 of Annex XI to the REACH Regulation, inter alia, provides that '[a]pplication 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)'. In addition, the Agency's margin of discretion is reflected in the use of the word 'may' in the relevant provisions of the legislation. Thus, Article 41(3) of the REACH Regulation provides that '[...] the Agency may [...] prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements'.

112. The Board of Appeal observes that the Agency's margin of discretion under Annex XI applies to the assessment of the adaptations proposed to the standard testing regime. The margin of discretion also applies when the Agency assesses whether it is, from the data for a reference or source substance(s), possible to predict the effects on human health or on the environment health of another (target) substance(s) for a particular endpoint.

113. It can be inferred from Annex XI that the application of read-across as a way to adapt the standard testing regime always entails a degree of uncertainty which the Agency has to assess. The Board of Appeal recognises that it is for the Agency to consider whether this uncertainty is acceptable or not.

114. Nevertheless, the Board of Appeal also underlines, that the fact that the Agency has a margin of discretion does not prevent the Board of Appeal from assessing whether that discretion was correctly used. In particular, this discretion requires that the Agency must be able to show that in adopting the act it actually exercised its discretion correctly, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate (see by analogy Case C-343/09 *Afton Chemical*, [2010] ECR I-7023, paragraphs 33 and 34; and decision of the Board of Appeal of 29 April 2013 in case A-005-2011, paragraph 77).

115. First, the Board of Appeal needs to consider the Appellant's claims concerning Article 25(1) of the REACH Regulation and the need to ensure that testing on vertebrate animals is undertaken only as a last resort. The Appellant, supported by the intervener, in essence claims that the Agency, by failing to weigh the principle of animal welfare against the need to undertake the imposed study, completely neglected the last resort principle and thus misused its margin of discretion.

116. The Board of Appeal observes 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 this case, which concerned a standard information requirement, Article 13(1) of the REACH Regulation requires the use of read-across if the conditions of that Article and Section 1.5 of Annex XI are met. The Agency's role in this respect is to evaluate whether the requirements of Section 1.5 of Annex XI have been met. The Board of Appeal considers that Article 25(1) of the REACH Regulation does not impose any additional duties on the Agency when a read-across proposal has been made beyond evaluating the proposal. The Appellant's claim in this regard is therefore rejected as unfounded.

117. The Board of Appeal observes that in the present case, and with regard to avoiding unnecessary testing on animals, the Agency accepted the read-across proposal for the Substance for the 90-day sub-chronic repeated dose toxicity study and rejected the read-across proposal for the Substance for the pre-natal developmental toxicity study.

Furthermore, the Board of Appeal observes that the Agency requested an in-vitro study before it came to a conclusion with regard to the read-across proposed for the pre-natal developmental toxicity endpoint.

118. The Board of Appeal considers that a second relevant factor in the circumstances of the present case that should have been considered by the Agency concerns the Appellant's claim that the read-across approach for the Substance and the endpoint on pre-natal developmental toxicity has been accepted in the OECD SIDS Report on Propylene Glycol Ethers. The Board of Appeal will therefore examine whether the Agency took this into account.

119. As stated in paragraph 96 above, the Appellant argues that the Agency failed to take into account in the Contested Decision the fact that the proposed read-across approach has been entirely accepted in the OECD's SIDS report on Propylene Glycol Ethers. In that regard, as also indicated in paragraph 96 above, the OECD's assessment contained a prerequisite of rapid hydrolysis. After obtaining the results of the in-vitro toxicokinetic study of the hydrolysis of the Substance to DPM, the Agency however considered that the hydrolysis of the Substance is not sufficiently rapid to ensure that there is no systemic availability of the Substance. The Board of Appeal therefore concludes that this factor was considered by the Agency.

120. The third factor that the Board of Appeal considers to be relevant and will therefore be considered concerns the question of whether or not the level of uncertainty resulting from the proposed read-across approach is acceptable. Throughout the decision-making process and in its written and oral submissions throughout the appeal proceedings, the Agency has consistently and coherently reiterated its concern over the rate of hydrolysis of the Substance and its consequences for systemic availability of the Substance and the possible toxicological impact of the presence of an acetate group on the Substance compared to the source substances. The Agency has maintained its concerns even after consideration of a significant amount of information submitted during the appeal procedure, including the results from the PBPK model and the paper on toxicology of other P-series glycol ethers. The Agency concluded that the evidence available to it only leads to speculation on the absence of potential teratogenic effects and that the consequent level of uncertainty is unacceptable. The Board of Appeal notes that the Appellant has not managed to adequately rebut the fact that its read-across proposal for the endpoint on pre-natal developmental toxicity contains a level of uncertainty considered to be unacceptable by the Agency. Referring to the precautionary principle and in order to ensure the safe use of the Substance according to the objectives of the REACH Regulation, the Agency pointed out in its written submissions and during the hearing, that in the circumstances of the present case, where it had evidence from an *in vitro* study showing that 10% of the Substance remains in the body for 36 minutes, it wanted to further investigate whether the Substance may or may not have any adverse effects with regard to pre-natal developmental toxicity. In addition, the Agency highlighted that the lack of information in relation to developmental toxicity prompted it to require additional information concerning the pre-natal developmental toxicity endpoint.

121. As already stated in paragraph 112 above, the Board of Appeal considers that, when assessing adaptations of the standard testing requirements using a grouping or read-across approach, as referred to in Section 1.5 of Annex XI to the REACH Regulation, and deciding whether or not the information available for the reference or source substance(s) can be used to adequately predict the human health and environmental properties of the target substance, the Agency possesses a margin of discretion. In such cases, the Agency has the responsibility to verify the information contained in the registration dossier and to verify, in particular, that the proposed adaptation complies with the relevant requirements.

122. In the present case, in view of the evidence presented and heard during the proceedings, the Board of Appeal considers that, when concluding that the proposed read-across adaptation from DPM to the Substance cannot be accepted, the Agency

took into account all the relevant factors and circumstances of the situation that the Contested Decision intended to regulate.

123. The Board of Appeal considers that the above conclusion is not brought into question by the Appellant's reference to the information on toxicological properties of the P-series glycol ethers and the results of the PBPK model as the Agency adequately addressed these aspects both during the appeals procedure and at the hearing.

124. In relation to the information on P-series glycol ethers, the Board of Appeal notes that that information does not address the Agency's concerns related to the possible adverse effects of the DPMA. Moreover, the Appellant itself stated in its comments on the draft decision of 29 November 2010 and again in its comments on the draft decision of 16 August 2011 that no developmental toxicity studies are available for the Substance and concluded that a developmental toxicity study with the Substance will be 'unlikely' to result in any adverse effects.

125. In relation to the PBPK model, the Board of Appeal first observes that the in-vitro toxicokinetic study, already mentioned in paragraph 120 above, revealed that the calculated amount and the period of the administered Substance available in the body cannot be regarded as negligible. Second, in relation to the question on the link between the teratogenic potential of the Substance and the rate of its hydrolysis, the Agency mentioned during the hearing, that there are two concerns present. The first concern is that the toxic effects of the substance to a number of targets in a developing organism are unknown. The second concern relates to a lack of data on the developmental toxicity of the Substance. The Agency added that the data relating to hydrolysis used in the PBPK model, still shows, like the results of the in-vitro toxicokinetic study, that the Substance is predicted to be present in the rat body and will be eliminated over some hours. The Agency concluded that it was this duration of the Substance's presence in the body that initially prompted the Agency to request that the pre-natal developmental toxicity study is performed with the Substance. The Board of Appeal recognises that, by requesting the study, the Agency also acted in accordance with the precautionary principle that underpins the provisions of the REACH Regulation as referred to in Article 1(3) of the REACH Regulation (see, to that effect, Case C-558/07, cited in paragraph 103 above, paragraph 54).

126. For the above reasons, the Board of Appeal concludes that the Agency correctly exercised its powers when it evaluated the read-across proposal made by the Appellant in light of the criteria set out in Section 1.5 of Annex XI of the REACH Regulation. The Agency was therefore acting within its margin of discretion in rejecting the read-across proposal for pre-natal developmental toxicity and, consequently, in requesting the study for the pre-natal developmental toxicity endpoint.

127. As a result, the Board of Appeal dismisses the Appellant's complaint alleging material illegality of the Contested Decision as unfounded.

128. It follows from all the above considerations that the appeal must be dismissed in its entirety.

III. Other issues under examination

1. Appeal fee

129. Regarding the Appellant's request to refund the appeal fee, the Board of Appeal notes that 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.

130. As the Board of Appeal has not decided the appeal in favour of the Appellant, the appeal fee shall not be refunded.

2. Effects of the Contested Decision

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

132. The Contested Decision, upheld in the present appeal proceedings, required the registrant, now the Appellant, to submit the required information by 24 October 2012, i.e. 12 months from the date of decision. The deadline to provide the requested information had thus expired in the course of the present appeal proceedings.

133. In the light of the above and taking into account the circumstances of the present case, a new time-limit should be set for the Appellant to submit the missing information, required by the Contested Decision.

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

ORDER

On those grounds,

THE BOARD OF APPEAL

hereby:

Dismisses the appeal.

Decides that the appeal fee shall not be refunded.

Decides that the Appellant shall submit the information, as required by Decision CCH-D-0000001716-72-04/F of 24 October 2011 adopted by the European Chemicals Agency, within 12 months from the date of notification of the Board of Appeal's decision in case A-001-2012.

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal