EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

10 October 2013

(Compliance check of a registration – New information - Section 8.7.2 of Annexes IX and X – Duty to state reasons – Assessment of waiving arguments)

Case number	A-004-2012
Language of the case	English
Appellant	Lanxess Deutschland GmbH Deutschland
Representative	Ursula Schliessner and Nicolas Croquet McKenna Long & Aldridge LLP Brussels Belgium
Intervener	The European Coalition to End Animal Experiments (ECEAE) United Kingdom Represented by: Katy Taylor and David Thomas London United Kingdom
Contested decision	CCH-D-0000002044-86-04/F of 5 April 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), Andrew FASEY (Technically Qualified Member and Rapporteur) and Barry DOHERTY (Legally Qualified Member)

Registrar: Sari HAUKKA

gives the following

Decision

RELEVANT LEGISLATION

1. Article 10(a)(vii) of the REACH Regulation provides:

   'A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:
   (a) a technical dossier including:
   […]
   (vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I.'

2. Article 12(1) of the REACH Regulation provides:

   'The technical dossier referred to in Article 10(a) shall include under points (vi) to (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:
   (a) the information specified in Annex VII for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex III, manufactured or imported in quantities of one tonne or more per year per manufacturer or importer;
   (b) the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III;
   (c) the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;
   (d) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;
   (e) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annexes IX and X for substances manufactured of imported in quantities of 1 000 tonnes or more per year per manufacturer or importer.'

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) of the REACH Regulation provides:

   '*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 dossiers(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.'

5. Article 41(3) of the REACH Regulation provides:

'*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.'*

6. Article 91(2) of the REACH Regulation provides:

'An appeal lodged pursuant to paragraph 1 shall have suspensive effect.'

7. 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*.'

8. The first paragraph of Annex VI to the REACH Regulation provides:

'Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 10, 12, 13, 40, 41 and 46. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.'

9. The second paragraph of Step 4 to Annex VI to the REACH Regulation provides:

'In some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.'

10. The first paragraph of the introduction to Annex VII to the REACH Regulation provides:

'Column 1 of this Annex establishes the standard information required for:
(a) non-phase-in substances manufactured or imported in quantities of 1 to 10 tonnes;
(b) phase-in substances manufactured or imported in quantities of 1 to 10 tonnes and meeting the criteria in Annex III in accordance with Article 12(1)(a) and (b); and
(c) substances manufactured or imported in quantities of 10 tonnes or more.'

11. The first paragraph of the introduction to Annex VIII to the REACH Regulation provides:

'Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 10 tonnes or more in accordance with Article 12(1)(c). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annex VII ….'

12. The second paragraph of the introduction to Annex IX to the REACH Regulation provides:

'Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 100 tonnes or more in accordance with Article 12(1)(d). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII and VIII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.'

13. Column 1 (Standard information required) of Section 8.6.2 of Annex IX to the REACH Regulation provides:

'Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.'

14. Column 1 (Standard information required) of Section 8.7.2 of Annex IX to the REACH Regulation provides:

'Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Commission Regulation on test methods as specified in Article 13(3) or OECD 414).'

15. Column 2 (Specific rules for adaptation from Column 1) of Section 8.7.2 of Annex IX to the REACH Regulation provides:

'*The Study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.*'

16. The second paragraph of Annex X to the REACH Regulation provides:

'Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 1 000 tonnes or more in accordance with Article 12(1)(e). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII, VIII and IX. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.'

17. Column 1 (Standard information required) of Section 8.7.2 of Annex X to the REACH Regulation provides:

'Developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (OECD 414).'

18. The introduction to Annex XI to the REACH Regulation provides:

'Annexes VII to X set out the information requirements for all substances manufactured or imported in quantities of:
- one tonne or more in accordance with Article 12(1)(a),
- 10 tonnes or more in accordance with Article 12(1)(c),
- 100 tonnes or more in accordance with Article 12(1)(d), and
- 1 000 tonnes or more in accordance with Article 12(1)(e).
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.'

SUMMARY OF THE FACTS

Background to the dispute

19. On 28 February 2011, the Agency initiated a compliance check of the Appellant's registration dossier for triphenyl phosphate (hereinafter the 'Substance').

20. On 2 May 2011, the Agency notified the draft decision to the Appellant and invited it to provide comments. The draft decision included a number of information requirements including requirements to provide information on sub-chronic toxicity (90-day) in the rat via the oral route (Section 8.6.2 of Annex IX to the REACH Regulation; European Union (hereinafter 'EU') Test Method B.26 or the Organisation for Economic Co-operation and Development (hereinafter 'OECD') Test Guideline 408) and a developmental toxicity study in the rabbit via the oral route (Section 8.7.2 of Annex X to the REACH Regulation; EU Test Method B.31 or OECD Test Guideline 414). Section III(e) of the draft decision also included the following reasoning '[a] prenatal developmental toxicity study on a first species is required under Annex IX, 8.7.2 to the REACH Regulation, and a developmental toxicity on a second species is required according to Annex X, 8.7.2, subject to all appropriate column 2 or Annex XI data adaptations. ECHA observes that in the technical dossier, the Registrant has provided data on developmental toxicity, and no adverse effects on prenatal development were observed in a study of the first species. However, there is no information provided for the prenatal developmental toxicity test on a second species, nor is there any adequate adaptation of the information requirement. Therefore there is an information gap'.

21. On 1 June 2011, the Appellant submitted comments on the draft decision and, on 2 September 2011, updated its registration dossier. In the updated registration dossier a number of the information gaps identified in the draft decision were filled and the Agency accordingly removed the corresponding information requirements from the draft decision.

22. On 4 November 2011, the Agency notified the Competent Authorities of the Member States (hereinafter the 'MSCAs') of the draft decision. Subsequently, following proposals for amendment from certain MSCAs, the Agency modified the draft decision.

23. On 8 December 2011, the Agency notified the Appellant of the proposals for amendment to the draft decision and invited it to provide comments on the proposals, which it duly did on 9 January 2012.

24. On 19 December 2011, the draft decision was referred to the Member State Committee (hereinafter the 'MSC') which reached a unanimous agreement on the draft decision on 8 February 2012.

25. On 5 April 2012, the Agency adopted the Contested Decision which requests the Appellant to provide the following information using the test methods indicated:

    - Sub-chronic toxicity (90-day) in the rat via the oral route (Section 8.6.2 of Annex IX to the REACH Regulation; EU Test Method B.26 or OECD Test Guideline 408); and
    - Developmental toxicity study in the rabbit via the oral route (Section 8.7.2 of Annex X to the REACH Regulation; EU Test Method B.31 or OECD Test Guideline 414).

    The Appellant was required to submit this information in the form of an updated dossier by 5 April 2014.

26. In relation to the requirement to provide information on a developmental toxicity study in the rabbit, Section III(b) of the Contested Decision states that the Agency '… observes that in the technical dossier, the Registrant has provided data on developmental toxicity, and no adverse effects on prenatal development were observed in a study on the first species. However, there is no information provided for the pre-natal developmental toxicity test on a second species, nor is there any adequate adaptation of the information requirement. There is therefore an information gap'. Section III(1)(b) of the Contested Decision also states that '…it follows from the information in Annexes IX and X, 8.7.2 that a first species test is to be conducted at the tonnage band of 100 to 1 000 tonnes per year and where deemed necessary already at this level, a second species test may be necessary. The second species test then becomes a default requirement at a tonnage band of 1 000 tonnes or more. Otherwise there would be no need to restate as information requirement for this study at Annex X level'.

Procedure before the Board of Appeal

27. On 5 July 2012, the Appellant lodged the present appeal at the Registry of the Board of Appeal in which it requested the Board of Appeal to:

    - Revise the Contested Decision so as to allow the Appellant to update its dossier by 31 December 2014 with the results of a 13-week (Dosed-Feed) sub-chronic toxicity study on mice expected to be initiated by the United States National Toxicology Program (hereinafter the 'NTP Study') by the end of 2012;
    - Annul the Contested Decision to the extent that it requires the Appellant to conduct a pre-natal developmental toxicity study in the rabbit (second species) via the oral route; and
    - Reimburse the fees for, and costs arising from, the appeal proceedings.

28. On 13 August 2012, ECEAE applied to intervene in the proceedings before the Board of Appeal in support of the Appellant. On 14 August 2012, the application to intervene was notified to the Appellant and the Agency. The Appellant and the Agency submitted observations on the application to intervene on 5 and 6 September 2012 respectively. By a decision dated 26 September 2012, the Board of Appeal granted the application to intervene.

29. On 6 September 2012, the Agency submitted its Defence to the Registry of the Board of Appeal.

30. By letter dated 11 September 2012, the Appellant was invited to submit its observations on the Agency's Defence. On 9 October 2012, the Appellant duly lodged its observations on the Defence.

31. On 29 October 2012, ECEAE submitted its observations on the procedural documents submitted in the case to that point. On 31 October 2012, the Board of Appeal invited the Appellant and the Agency to submit their observations on the ECEAE's observations. The Agency and the Appellant submitted their observations on ECEAE's observations on 28 and 29 November 2012 respectively.

32. On 15 November 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 the Rules of Procedure, designated an alternate member, Barry Doherty, to act in the present case as the legally qualified member of the Board of Appeal.

33. On 16 November 2012, the Board of Appeal invited the Agency to submit observations on the Appellant's observations on the Defence. On 29 November 2011, the Agency duly submitted its observations.

34. On 10 December 2012, the Board of Appeal sent a number of written questions to the Agency and the Appellant. At the same time the Board of Appeal also invited the Parties to discuss between them the possibility of reaching an agreement regarding a particular issue concerning the Appellant's first claim. The Agency and the Appellant responded to the Board of Appeal's questions on 16 and 18 January 2013 respectively. In those communications the Board of Appeal was informed that the Agency considered that it was not in a position to reach an agreement on the issue raised by the Board of Appeal concerning the first claim.

35. On 6 February 2013, the Board of Appeal invited the Agency to respond to a number of additional written questions. The Agency's reply was duly received on 21 February 2013.

36. On 27 February 2013, the Board of Appeal sent further written questions to the Agency and invited the Appellant to respond to the Agency's submission of 21 February 2013. The Agency and the Appellant both responded on 20 March 2013.

37. On 27 March 2013, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure.

38. On 3 April 2013, the Appellant informed the Board of Appeal that it did not request a hearing to be held. On 10 April 2013, the Agency responded that in its latest submission the Appellant had raised new arguments regarding the scope of the Board of Appeal's powers of review. The Agency claimed that those arguments should not be taken into consideration by the Board of Appeal but that if they were it requested the opportunity to respond. To this end, the Agency requested either an oral hearing to be held or the re-opening of the written procedure.

39. On 2 May 2013, the Registry informed the Parties and the Intervener that the Board of Appeal had decided to organise a meeting pursuant to Article 15(3)(e) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter the 'Rules of Procedure'), to allow the Agency to respond to the Appellant's arguments concerning the scope of the Board of Appeal's powers of review.

40. On 13 May 2013, the Appellant and the Agency informed the Registry that they agreed to the proposed meeting. In particular, the Agency agreed to the meeting being held in lieu of a full oral hearing.

41. In addition, the Appellant's submission of 13 May 2013 contained a request to submit proposed new evidence related to the possible timing of the NTP Study. This proposed new evidence consisted of an email of 26 April 2013 from the United States National Institute of Environmental Health Science (hereinafter the 'NIEHS') in which the Appellant was informed that the United States National Toxicology Program (hereinafter the 'NTP') no longer anticipates conducting the NTP Study in 2013 and that the time-line for the study remains uncertain. The Appellant stated that on the basis of the proposed new evidence, namely the email of 26 April 2013, the Appellant would also like to comment on the implications of this new time-line and ultimately request an extension of the deadline set out in its first claim, which would now be for three years as of the date of notification to the Appellant of the Board of Appeal's decision on the appeal.

42. On 17 May 2013, the Board of Appeal adopted a decision rejecting the Appellant's request to submit new evidence on the grounds that the Appellant had not sufficiently justified the delay in offering the evidence as required by Article 12(1) of the Rules of Procedure.

43. On 11 June 2013, a meeting was held via telephone conference at which the Parties and the Intervener provided observations on the question of the Board of Appeal's powers of review.

REASONS

Claims under Examination

1. Appellant's request for the Board of Appeal to revise the Contested Decision to allow it to use the results of the NTP Study

Arguments of the Parties

44. The Appellant firstly requests the Board of Appeal to revise the Contested Decision so as to allow it to update its registration dossier by 31 December 2014 with the results of the NTP Study, which was expected to be initiated by the NTP by the end of 2012.

45. The Appellant, supported by the Intervener, argues that it should be permitted to rely on the results of the NTP Study instead of having to 'duplicate' a 90-day sub-chronic test on another rodent as required by the Contested Decision. The Appellant argues therefore that it should be entitled to submit an updated registration dossier once the NTP Study results become publicly available.

46. The Appellant also argues that Section 8.6.2 of Annex IX to the REACH Regulation requires a 90-day sub-chronic toxicity study on rodents and therefore the NTP Study on mice is suitable to replace the 90-day sub-chronic toxicity study on the rat required in the Contested Decision. The Appellant adds that the protocol for the NTP Study indicates that 90-day toxicity studies conducted under the NTP will include information on all toxicologically relevant parameters.

47. The Appellant claims that information regarding the NTP Study is new and consequently could not have been taken into consideration in its registration dossier or in the Agency's decision-making process. However, the Appellant argues that the Board of Appeal has the full right of review of facts and law up until the time it has to issue its decision and, therefore, can take into account new information raised at the appeal stage.

48. The Agency argues that the Appellant's first claim is inadmissible as the Notice of Appeal does not contest the lawfulness of the Contested Decision. The Agency adds that the Notice of Appeal does not contain any pleas in law regarding the first claim and that according to the REACH Regulation and the Rules of Procedure, the Board of Appeal may only address pleas challenging the legality of the Agency's decisions.

49. In the alternative, the Agency claims that the Appellant's first claim is unfounded on the grounds that the achievement of the dossier evaluation objective requires that all Agency decisions specify as precisely and objectively as possible the information required. To this end, for the purposes of Annexes VII to X of the REACH Regulation, the Agency has to require a specific test to be carried out. The Agency states that the addressee of a dossier evaluation decision can nonetheless meet a particular information requirement by means other than by conducting the study specifically required in that decision. The Agency adds however that in such cases there is a risk that the Agency may come to the conclusion that the information submitted further to a dossier evaluation is insufficient to comply with the information requirement in the Contested Decision. In such cases the Agency would inform the Member State concerned that the compliance check decision had not been complied with and that Member State would then be competent to decide on possible enforcement action. The Agency does not contest therefore that the Appellant could submit the results of the NTP Study, if available, in response to the Contested Decision. The Agency highlights however that the Appellant would run the risk of later being found to be incompliant with the Contested Decision.

50. The Agency also argues that decisions adopted under Title VI of the REACH Regulation, which includes Article 41, cannot be based on uncertain future events, such as the completion of testing by a third party not subject to the requirements imposed by the REACH Regulation. The Agency adds that its decisions do not have any binding effect on third parties such as the NTP with regard to the timing of the performance of tests.

51. The Agency also claims that the information filed in the appeal could have been provided during the dossier evaluation phase as the Appellant has not demonstrated that the information is new.

52. The Agency argues that the factual basis for the Agency's decision-making under dossier evaluation is established and cannot be altered by registrants after the draft decision has been sent to the MSCAs pursuant to Article 51(1) of the REACH Regulation. Consequently, according to the Agency, the information concerning the NTP Study that was presented in the Notice of Appeal cannot be taken into consideration during the appeals process.

53. The Agency also claims that the Appellant's request for an extension of the time limit to provide information on sub-chronic toxicity has not been substantiated. The Agency argues that the evidence provided by the Appellant does not specify when the NTP expects to make the results of its test available.

Findings of the Board of Appeal

54. The Board of Appeal is required to examine whether the time limit set in the Contested Decision to provide the sub-chronic toxicity study should be extended from 5 April 2014 to 31 December 2014 to allow the Appellant to take into account the results of the NTP Study.

55. Without examining the Agency's arguments related to the admissibility of the first claim, the Board of Appeal observes that the time-line regarding the performance of

the NTP Study is, and has always been, uncertain. Furthermore, the Appellant has no control or influence over when the NTP Study will be performed or when the results thereof are made publicly available. Even at the time of the submission of the Notice of Appeal it was clearly foreseeable that the results of the NTP Study might not be available by 31 December 2014, the revised deadline requested by the Appellant in the present proceedings. Indeed, during the present appeal proceedings, the Appellant itself conceded that the results of the NTP Study may not be available by that date but that it was willing to take that risk. It also became clear during the proceedings that the provisional timing of the NTP Study was subject to delay.

56. The Board of Appeal observes that the uncertainty regarding the timing of the NTP Study is demonstrated by the evidence submitted during the proceedings. The Appellant maintains, although it was not possible to clarify with certainty, that the announcement of the intention to perform the NTP Study was first made available on the NTP's website on 20 May 2012. However, even by the time of the last submissions in the present proceedings there was no certainty as to when the results of the NTP Study would be publicly available. For example, as part of its Notice of Appeal the Appellant submitted an email of 14 June 2012 from the NIEHS in which it is stated that the NTP Study is '… due to be conducted this year…' and that the NIEHS does not have '… a more specific date for when these studies will begin at this time'. In its observations on the Defence, the Appellant subsequently submitted an email from the NIEHS of 14 August 2012 in which it is stated that '… it is possible that the in-life portion of the 13 [week] mouse study will be completed by April 2014. Due to additional time required for pathology and other reviews and analyses, it is very unlikely that study data will be publicly available by that time.'

57. Furthermore, in an email of 19 December 2012 from the NIEHS submitted by the Appellant during these proceedings it is stated that '… [s]tudy designs for [the Substance] were finalised in January 2012 … NTP studies are initiated as time and resources permit. Unfortunately, there is no exact time line for when the [Substance] studies will begin. We anticipate conducting … the 14-day study in mice in 2013'. In that email no exact time-line for the planned 13-week study was specified.

58. The Board of Appeal observes that even if it had accepted the evidence submitted by the Appellant regarding the timing of the NTP Study, which was rejected by the Board of Appeal in its Decision of 17 May 2013, that evidence would have confirmed that no dates have been fixed for the performance or finalisation of the NTP Study.

59. The Board of Appeal also notes that, as stated by the Agency, in accordance with the REACH Regulation the information on sub-chronic toxicity requested in the Contested Decision should have already been made available to the Agency in the Appellant's registration dossier. The Appellant has not challenged the Agency's decision to request that information. The Board of Appeal considers that the provision of that information should not be further delayed by uncertain future events which are outside the control of the Appellant.

60. In conclusion, the Board of Appeal finds that the timing of the NTP Study is uncertain and outside the control of the Appellant. The evidence submitted in the case provides no certainty that the results of the NTP Study will be available in the near future or even by 31 December 2014. As a result, the performance of the NTP Study at some unspecified time in the future cannot justify the revision of the Contested Decision with respect to the information required on sub-chronic toxicity.

61. The Appellant's request for the Board of Appeal to revise the Contested Decision to allow it to take into account the results of the NTP Study must therefore be dismissed,

without it being necessary to decide separately on the Agency's plea that the first claim is inadmissible.

2. Appellant's request to annul the Contested Decision to the extent that it requires the Appellant to conduct a pre-natal developmental toxicity study in the rabbit (second species) via the oral route

62. The Appellant secondly requests the Board of Appeal to annul the Contested Decision to the extent that it requires the Appellant to conduct a pre-natal developmental toxicity study in the rabbit (as a second species) via the oral route. In support of this claim the Appellant presents four pleas.

63. By its first plea the Appellant claims that the Agency incorrectly interpreted Column 1 of Section 8.7.2 of Annex X to the REACH Regulation. By its second plea the Appellant argues that the Agency breached its duty to state reasons. By its third plea the Appellant argues that the Agency incorrectly assessed the Appellant's waiving arguments. Finally, by its fourth plea, the Appellant argues that the Agency failed to consider the available data on the very low consumer exposure to the Substance for waiving the information requirement. The Board of Appeal will examine the Appellant's first, third and fourth pleas in turn before turning its attention to the Appellant's second plea.

(i) The Appellant's first plea regarding the Agency's incorrect interpretation of Section 8.7.2 of Annex X

Arguments of Parties

64. The Appellant claims that Column 1 of Section 8.7.2 of Annex X to the REACH Regulation, read in the light of Column 1 of Section 8.7.2 of Annex IX, does not support the Agency's interpretation that a pre-natal developmental toxicity study on a second species is a standard information requirement for substances manufactured or imported in quantities of 1 000 tonnes or more per year (hereinafter the 'tonnage band of 1 000 tonnes or more per year'). In particular, the Appellant claims that there is no mention of a default information requirement for a second species study anywhere in Column 1 of Annexes VII to X to the REACH Regulation. The Appellant adds that had the drafters of the REACH Regulation intended to require information on a second species in Column 1 of Annex X this would have been mentioned directly in the provision.

65. The Appellant also claims that Column 2 of Section 8.7.2 of Annex IX states that the Agency may impose a study on a second species not only for substances manufactured or imported in quantities of between 100 and 1 000 tonnes per year (hereinafter the 'tonnage band of 100 to 1 000 tonnes per year') but also at the tonnage band of 1 000 tonnes or more per year contingent upon the outcome of the first species study and all other relevant available data. According to the Appellant, if the Agency's reasoning were applied, the text of Column 2 of Annex IX would become redundant since the second species study would in any event have to be carried out as a standard information requirement under Annex X regardless of any individual adaptation assessment.

66. The Appellant claims further that the Agency's interpretation of Section 8.7.2 of Annex X to the REACH Regulation is inconsistent with the underlying system of the REACH Regulation. The Appellant claims that the drafters of the REACH Regulation had

intended to require testing on a second species only in exceptional cases, requiring further sacrificing of animals only when testing on the first species proves to be insufficient to achieve clarity. The Appellant claims that its interpretation is in line with Article 25(1) and Recital 47 of the REACH Regulation.

67. The Appellant also argues that its interpretation of Section 8.7.2 of Annex X complies with the general principle of proportionality which requires that additional testing may be imposed only if suitable and necessary to achieve a legitimate objective underpinning the Annex IX and X information requirements, in other words public health. The Appellant also argues that there is no scope for the Agency to use proportionality considerations where the legislator explicitly refrained from imposing a standard second species testing requirement. The Appellant claims that where the text of the legislation is so clear that it leaves no scope for reasonable doubt as to its interpretation the object and purpose of that legislation cannot be used as a reason to depart from the specific provisions contained therein. The Agency's Defence argues that the preparatory work leading to the adoption of the REACH Regulation demonstrates that it was the explicit intention of the legislator to impose testing on two species. In response, the Appellant argues that the evidence presented by the Agency during the appeal proceedings does not support this argument.

68. The Agency argues that its interpretation of Section 8.7.2 of Annex X to the REACH Regulation as set out in the Contested Decision is fully justified by the scientific context of the provision and is consistent with other similar legislation requiring the assessment of chemical substances. In response to this claim, the Appellant argues that second species testing is not a standard information requirement in all circumstances, for example, for veterinary medicinal products or under Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

69. The Agency considers that the requirement of testing on a second species is suitable and necessary to achieve the objectives of the REACH Regulation, in particular having regard to the fact that the objectives of the protection of human health and the environment in the identification of hazardous properties take precedence over the other objectives of the REACH Regulation. The Agency considers that its interpretation is proportionate to all the objectives and interests pursued by the REACH Regulation, as well as its legislative history (see paragraph 67 above)

70. The Intervener argues that the Agency was incorrect to require a second species study as a default requirement under Section 8.7.2 of Annex X. The Intervener considers inter alia that, given the low toxicity profile of the Substance, the low exposure risk and the evidence that a second species study does not generally improve predictivity of pre-natal development in humans such a study would be disproportionate.

Findings of the Board of Appeal

71. According to the statement of reasons set out in the Contested Decision and cited in paragraph 26 above, the Appellant's registration dossier contained an information gap as it did not include any information on the pre-natal developmental toxicity endpoint on a second species, nor did it include any adequate adaptation of the information requirement. In this respect, the Contested Decision states inter alia that '… it follows from the information in Annexes IX and X, 8.7.2 that a first species test is to be conducted at the tonnage band of 100 to 1 000 tonnes per year and where deemed necessary already at this level, a second species test may be necessary. The second species test then becomes a default requirement at a tonnage band of 1 000 tonnes or more …'.

72. As a preliminary observation, the Board of Appeal notes that the information requirements set out in Column 1 of Annexes VII to X to the REACH Regulation are cumulative. This principle is set out in the first paragraph of Annex VI cited in paragraph 8 above. The introduction to each of the Annexes listing the information requirements (i.e. Annexes VII to X; hereinafter the 'testing Annexes'), including the second paragraph of Annex X cited in paragraph 16 above, repeats this point. The Board of Appeal also notes that an information requirement concerning pre-natal developmental toxicity is not found in Annexes VII or VIII and is therefore set out for the first time in Section 8.7.2 of Annex IX.

73. As a result of the cumulative nature of the requirements contained in Column 1 to the testing Annexes, the Board of Appeal considers that, pursuant to Section 8.7.2 of Annex X, registrants are required to perform a developmental toxicity study on a species other than the species used in the performance of the pre-natal developmental toxicity study under Column 1 of Section 8.7.2 of Annex IX, unless one or more of the adaptations in Section 8.7 of Annex X or Annex XI apply.

74. The Board of Appeal considers that this finding is not affected by the Appellant's argument that Section 8.7.2 of Annex X to the REACH Regulation cannot be considered to be a default information requirement due to the explicit wording of Column 2 of Section 8.7.2 of Annex IX. In view of the Appellant's arguments, the Board of Appeal will now examine the meaning of Column 2 of Section 8.7.2 of Annex IX.

75. The Board of Appeal considers firstly that there is no wording in the Annexes to the REACH Regulation to suggest that the provisions contained in Column 2 of the testing Annexes are cumulative. This view is supported for example by the use of identical wording for the adaptations under Column 2 of Section 8.7 of both Annexes IX and X. The Board of Appeal finds therefore that the rule contained in Column 2 of Section 8.7.2 of Annex IX does not carry across to Annex X.

76. It is also important to recall that Step 4 of Annex VI to the REACH Regulation cited above in paragraph 9 specifically refers to the fact that '[i]n some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements'. In other words, standard information requirements for higher tonnage levels may be, in some cases, brought forward to a lower tonnage band.

77. In this regard, the first sentence of Column 2 of Section 8.7.2 of Annex IX, which states that '[t]he study shall be initially performed on one species', clarifies the need for a registrant to satisfy the information requirement on one species at the Annex IX level, unless one or more of the adaptations in Section 8.7 or Annex XI apply. The second sentence of Column 2 of Section 8.7.2 of Annex IX states that '[a] decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data'. The Board of Appeal considers that this sentence is a concrete example of a requirement that a test required at a certain tonnage level is potentially undertaken at an earlier tonnage level. In other words, Column 2 of Section 8.7.2 of Annex IX requires a registrant to bring forward testing on a second species from Annex X to Annex IX if the results of the test on the first species show this to be scientifically justified. If a second species study was conducted at the tonnage band of 100 to 1 000 tonnes per year, that is to say under Section 8.7.2 of Annex IX, then there would be no need to conduct a further study at the tonnage band of 1 000 tonnes or more per year, that is to say under Section 8.7.2 of Annex X, as the relevant information should already have been included in the registration dossier.

78. The Board of Appeal finds therefore that the purpose of Column 2 of Section 8.7.2 of Annex IX is to bring forward the requirement to perform a study on a second species where the results of the first test and other available information show this to be justified.

79. It is important to note that a registrant's decision on whether to perform a pre-natal developmental study on a second species at the tonnage band of 100 to 1 000 tonnes per year and the reasons for that decision must be fully justified in the appropriate section of the registration dossier. This requirement is made clear for example in the second paragraph of the introduction to Annex IX cited in paragraph 12 above.

80. In the present case, however, since the Appellant manufactures the Substance at over 1 000 tonnes per year, the Appellant is not required to make the analysis whether to perform the study on a second species already under Annex IX. In other words, in effect, Column 2 of Section 8.7.2 of Annex IX is not applicable to the Appellant in the present case as the second species study is a standard information requirement under Annex X.

81. Furthermore, the Board of Appeal observes that, pursuant inter alia to Article 12 of the REACH Regulation, the higher the tonnage level at which a substance is manufactured or imported the stricter the information requirements become. Consequently, even if the provision contained in Column 2 of Section 8.7.2 of Annex IX would lead to more adaptation possibilities regarding the performance of the second species test at the tonnage band of 100 to 1 000 tonnes per year than the adaptations applicable to the tonnage band of 1 000 tonnes or more per year this would be in line with that principle.

82. The Board of Appeal also finds that the Appellant was incorrect in arguing that the Agency's interpretation of Column 2 of Section 8.7.2 of Annex IX and Column 1 of Section 8.7.2 of Annex X means that a study on a second species must in every instance be performed. In this respect, it must be highlighted that the REACH Regulation clearly provides that an information requirement may also be filled by means other than tests where justified. This rule is clearly set out in the introduction to each of Annexes VI to XI.

83. As with at the tonnage band of 100 to 1 000 tonnes per year, prior to conducting a developmental toxicity study on a second species at the tonnage band of 1 000 tonnes or more per year, a registrant should always evaluate the results of the first test, as well as all other available information, for the purposes of deciding whether the adaptations set out in Column 2 of Section 8.7 of Annex X or Annex XI apply. In other words, the Appellant will not be required to carry out a study on a second species at the Annex X level if existing information, including that generated from the study on the first species, shows that one of the adaptation possibilities mentioned in Column 2 of Section 8.7 of Annex X or Annex XI is applicable.

84. Registrants must always, however, clearly set out the reasons for proposing an adaptation in the appropriate section of the registration dossier. This requirement is made clear in the introduction to each of the testing Annexes. Annex X for example states that '… if the conditions are met under which Column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier'. Similarly, the introduction to each of the testing Annexes, including Annex X, states that '… a registrant may propose to adapt the required standard information set out in column 1 … according to the general rules contained in Annex XI. In this case as well, he shall clearly 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'. This does not, however, preclude registrants from making reference to other parts of their registration dossiers, for example the Chemical Safety Report, where this supports the reasons provided. It is therefore clear that the reasons for any adaptation or waiving must be clearly set out in the appropriate section of the registration dossier. The inclusion in the dossier of such specific reasoning is essential to allow the Agency to evaluate whether the registration information requirements have been met. In the present case, the Appellant's registration dossier did not contain such reasoning. The Agency was therefore correct in concluding that there was an information gap.

85. The Board of Appeal also observes that the Appellant's claim that the Agency's interpretation of Section 8.7.2 of Annexes IX and X would lead to second species studies always having to be carried out regardless of any individual adaptation assessment is not reflected in the Contested Decision itself. In this respect the Contested Decision states that '[b]oth information requirements are subject to all appropriate column 2 or Annex XI adaptations' and '… [h]owever, there is no information provided for the pre-natal developmental toxicity test on a second species, nor is there any adequate adaptation of the information requirement. Therefore there is an information gap'. In other words, according to the Contested Decision, and confirmed in the Agency's Defence in the present proceedings, although the possibility to adapt the information requirement existed, the Appellant had failed to avail itself of this possibility and provide reasons as to why information on a second species study was not required.

86. In conclusion, the Board of Appeal considers that the provisions of the REACH Regulation, when read as a whole, allow it to conclude that, in accordance with Section 8.7.2 of Annex X, registrants are required to perform a developmental toxicity study on a second species unless the adaptations set out in Column 2 of Section 8.7 of Annex X and Annex XI mean that such a test is not necessary.

87. For the above reasons, the Appellant's plea that the Agency had incorrectly interpreted Section 8.7.2 of Annex X must be rejected.

(ii) Appellant's third plea that the Agency incorrectly assessed its waiving arguments

Arguments of the Parties

88. The Appellant argues that the Agency wrongfully assessed its waiving arguments under Column 2 of Section 8.7.2 of Annex IX and Annex XI. The Appellant states that the results of the first species study established that the Substance has no effects on fertility or pre-natal developmental toxicity; as a result the need for a developmental toxicity study in a second species has not been triggered. In addition, the Appellant claims that there is no indication that rabbits are more sensitive to the Substance than rats, in light of an acute oral toxicity study and a repeated dose toxicity study. The Appellant also argues that the OECD Screening Information Data Set evaluation of the Substance concluded that a repeated dose toxicity study in the rabbit showed no effect on the reproductive organs up to the highest dose. The Appellant argues that in light of these study results, the waiving criteria in Column 2 of Section 8.7.2 of Annex IX and Annex XI to the REACH Regulation are met.

89. The Agency claims that the Appellant did not develop any arguments on adaptation as regards testing on a second species in its registration dossier. According to the Agency, the Appellant challenged only the existence of the principle of requiring testing on a second species under Annex X.

90. The Agency also claims that the only derogations from the requirement for testing on a second species are those explicitly provided for in Section 1.2 of Annex XI and Section 8.7 of Annexes IX and X to the REACH Regulation. While the Agency does not challenge the Appellant's claims that testing on the first species did not report any effects and that acute and repeated dose toxicity studies on the rabbit gave no indication that rabbits are more sensitive to the Substance, the Agency maintains that the test on a first species is not sufficient to remove the uncertainty as to the pre-natal developmental potency of the Substance.

Findings of the Board of Appeal

91. The Board of Appeal observes that, according to the Contested Decision, '…there is no information provided for the pre-natal developmental toxicity test on a second species, nor is there any adequate adaptation of the information requirement. Therefore there is an information gap'. Furthermore, the Appellant has not disputed the fact that it did not specifically include in the appropriate sections of the registration dossier arguments to support the waiving or adaptation of the need to perform a second species study either under Annex IX or Annex X.

92. As stated in paragraph 84 above, it is clear that registrants must clearly set out the reasons for their decision not to perform a study on the second species under either Annex IX or Annex X. This is essential to allow the Agency to assess the validity of the registrant's decision not to perform the test on the second species.

93. Since the Appellant did not clearly put forward adaptation or waiving arguments in the appropriate section of its registration dossier the Agency was not in a position to assess them. Furthermore, the Agency should not be required to compile adaptation arguments on behalf of registrants from the information set out in other parts of the registration dossier. Consequently, the Appellant's plea that the Agency incorrectly assessed the Appellant's waiving arguments must be rejected (see by analogy, for example, Joined Cases C-106/09 P and C-107/09 P *Commission and Spain v Government of Gibraltar and United Kingdom*, judgment of 15 November 2011, paragraphs 149 to 151).

(iii) Appellant's fourth plea regarding the Agency's alleged failure to consider exposure estimates on the very low consumer exposure to the Substance in the registration dossier as reasoning for waiving pursuant to Section 8.7.2 of Annex IX

Arguments of the Parties

94. The Appellant claims that the Agency failed to consider the available data on the very low consumer exposure to the Substance which the Appellant had presented in the Chemical Safety Report submitted as part of its registration dossier. The Appellant adds that a third party expert, contacted by the Appellant for the purposes of the appeal proceedings, concluded that consumer exposure to the Substance is estimated to be extremely low even in worst case situations, and is below the threshold for toxicological concern. Thus, based on information available in the registration dossier, a developmental toxicity study in the second species cannot be expected to have any relevant effect on risk characterisation, risk management measures and conditions for use of the Substance, and therefore the requested study is not scientifically justified. The Appellant considers that the Agency should have considered this point.

95. The Appellant states that it did not raise such arguments in its registration dossier as it had built its dossier on the premise that second-species testing was only required if the results of the first species testing were not sufficiently clear or there was other data of concern.

96. The Agency maintains that the Appellant did not raise such an argument during the decision-making process leading to the adoption of the Contested Decision. According to the Agency, it was not required to take into consideration the exposure information on its own initiative. Accordingly, the Agency considers that the adaptation proposed by the Appellant should be considered inadmissible as it was raised for the first time during the appeal proceedings.

97. In the alternative, the Agency maintains that the Appellant's arguments on exposure-based adaptation are not valid.

Findings of the Board of Appeal

98. As stated above in paragraphs 84 and 92, the Board of Appeal considers that it is clear from the REACH Regulation that registrants are required to clearly set out the reasons for any adaptations in the appropriate parts of the registration dossier. For example, the introduction to each of the testing Annexes state that registrants must '…clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier'.

99. It is also clear that the Appellant did not set out in the appropriate section of the registration dossier any arguments concerning low consumer exposure to the Substance as a justification for not providing information on a developmental toxicity study in a second species pursuant to either Annex IX or Annex X. Furthermore, the Board of Appeal considers that the Agency is not required to examine the registration dossier of its own initiative to look for information that may justify an adaptation or waiving.

100. The fact that the Appellant incorrectly interpreted the relevant provisions did not impose on the Agency, as claimed by the Appellant, the responsibility to scrutinise the registration dossier for possible adaptations. The Board of Appeal also considers that the Appellant's misinterpretation of Section 8.7.2 of Annexes IX and X was made known by the Agency in the draft decision of 2 May 2011, in particular in Section III(e) thereof cited above in paragraph 20. Consequently, the Board of Appeal considers that the Appellant had the opportunity to present justifications for adaptation related inter alia to low consumer exposure prior to the adoption of the Contested Decision.

101. In view of the above, the Appellant's plea that the Agency failed to consider for the purposes of adapting the information requirement the available data on the very low consumer exposure to the Substance must be rejected.

(iv) Appellant's second plea regarding the breach of the duty to state reasons

Arguments of the Parties

102. The Appellant claims that the Agency had failed to provide sufficient reasons for the Contested Decision as required by Article 41 of the Charter of Fundamental Rights of the European Union (OJ C 83, 30.3.2010, p. 389; hereinafter the 'Charter') and Article 296 of the Treaty on the Functioning of the European Union (hereinafter the 'TFEU'). In particular, the Appellant claims that the Agency's brief reasoning does not allow the

Appellant to understand the Agency's position that second-species testing is a standard information requirement at the tonnage band of 1 000 tonnes or more per year. The Appellant claims that a detailed justification was needed as the Agency's interpretation went against the very wording of the relevant provisions of the REACH Regulation. The Appellant also claims that the Agency should have provided reasons to justify its conclusions that the Appellant had not provided any adequate adaptation of the information requirement.

103. The Appellant and the Intervener also claim that there have been inconsistent and divergent interpretations of the relevant provisions by the Agency and MSC which would therefore increase the Agency's obligation to provide reasons for the Contested Decision.

104. The Agency maintains that its interpretation of the requirement for testing on a second species is reflected in the Agency's 'Guidance on information requirements and chemical safety assessment – Chapter R.7a: Endpoint specific guidance' (Version 1.0 of May 2008; hereinafter the 'Guidance'). Furthermore, the Agency claims that it had explained the principle underlying its position in the draft version of the Contested Decision. As the explanation reflected the Guidance document, the Agency maintains that it did not need to provide further factual or legal justifications as those provided enabled the Appellant to understand the Agency's position. The Agency considers that it clarified in the Contested Decision the difference between Annexes IX and X with regard to the requirement for testing on a second species. The Agency concludes that it has sufficiently reasoned its decision.

Findings of the Board of Appeal

105. 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 and Article 41(2)(c) of the Charter. According to the case-law of the European Courts, pursuant to those provisions, 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–719, paragraph 63).

106. 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).

107. According to the Contested Decision, the Agency's reasons for requiring information on a developmental toxicity study in a second species are that '…there is no information provided for the pre-natal developmental toxicity test on a second species, nor is there any adequate adaptation of the information requirement. Therefore there is an information gap'. The Board of Appeal observes that the Agency also clearly set out in the Contested Decision that it considered that, subject to adaptation possibilities, registrants are required to provide information on a developmental toxicity study on a second species pursuant to Section 8.7.2 of Annex X.

108. The Board of Appeal considers firstly that the Agency's arguments that the interpretation of Section 8.7.2 of Annex IX and X is made clear in the Guidance is not convincing. In fact, the Board of Appeal considers that rather than clarifying the interpretation of those provisions, the Guidance may, although not claimed by the Appellant in these proceedings, contribute to a misunderstanding thereof.

109. Nonetheless, as stated above in paragraphs 71 to 87, the Board of Appeal considers that the Agency had correctly interpreted Section 8.7.2 of Annex IX and Section 8.7.2 of Annex X in the Contested Decision. Consequently, the Agency's request for a second species study flows directly from the legislation. In such cases, as the Agency had no option but to require the missing information, the level of justification required is more limited.

110. In addition, the Board of Appeal observes that the Contested Decision also presents brief reasoning to address the Appellant's incorrect interpretation of the legislation presented in its comments on the draft decision. In this respect the Contested Decision states that '…it follows from the information in Annexes IX and X, 8.7.2 that a first species test is to be conducted at a tonnage band of 100 to 1 000 tonnes per year and where deemed necessary already at this level, a second species test may be necessary. The second species test then becomes a default requirement at a tonnage band of 1 000 tonnes or more. Otherwise there would be no need to restate as information requirement for this study at Annex X level'.

111. The Board of Appeal also notes that similar reasoning regarding the requirement to provide information on a developmental toxicity study in the second species was also presented in the draft decision of 2 May 2011. In this respect, it should be noted 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 C-15/10 *Etimine SA v Secretary of State for Work and Pensions*, [2011] ECR I-6681, paragraph 116).

112. In arguing that there have been divergent interpretations in the MSC on the provisions subject to this part of the appeal, the Appellant and the Intervener appear to argue that the MSC has been inconsistent in its approach regarding whether, before taking a decision on the need for a developmental toxicity study in the second species, the registrant should wait for the result of the first species study. The Board of Appeal considers however that the evidence provided on this point does not clearly support this alleged inconsistency.

113. In view of the above, the Board of Appeal considers that 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. The fact that the Appellant disagreed with the Agency's interpretation of the relevant provisions does not mean that the Agency failed to adequately state reasons for the Contested Decision.

114. With regard to the Appellant's claim that the Agency should have provided reasons as to why the Appellant had not provided any adequate adaptation of the information

requirement, the Board of Appeal has already found in paragraphs 91 to 93 and 98 to 101 above that the Appellant did not include sufficient justifications concerning possible adaptations in the relevant sections of its registration dossier. The Board of Appeal has also found in paragraphs 93 and 99 above that the Agency is not required to look for and create adaptations on behalf of registrants from the information available elsewhere in the dossier. As a result, the Agency was not required to provide a statement of reasons in that regard.

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 second plea of its second claim and, therefore, the appeal in its entirety must be dismissed.

3. Other issues under examination

(i) Appeal fee

116. 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.

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

(ii) Claim for reimbursement of costs

118. In its Notice of Appeal, the Appellant requests the Board of Appeal to order the Agency to reimburse the Appellant's costs arising from the appeal proceedings.

119. The Board of Appeal observes that there is no legal basis in the Rules of Procedure for the reimbursement of costs that are not, as provided in Articles 17 and 21(1)(h) thereof, related to taking of evidence in appeal proceedings.

120. Consequently, and as in the present case no costs arose in relation to taking of evidence, the Board of Appeal rejects the Appellant's request for reimbursement of costs that it incurred in the appeal proceedings.

(iii) Effects of the Contested Decision

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

122. The Contested Decision, upheld in the present appeal proceedings, required the Appellant to submit the required information within 24 months of the date of the adoption of the Contested Decision, in other words by 5 April 2014. 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 the light of the principle of suspensive effect laid down in Article 91(2) of the REACH Regulation, as if it referred to 24 months from the date of the final decision of the Board of Appeal.

123. During the proceedings the Agency stated, in response to a question on this issue from the Board of Appeal, that it considers that the suspensive effect of a contested decision applies until the decision of the Board of Appeal. The Agency considers that if the contested decision is upheld it becomes definitive and immediately becomes an obligation. The Board of Appeal notes that, with regard to the present case, the Agency's position would allow the Appellant only six months to provide the information required in the Contested Decision. The Agency has stated that the principle of proportionality requires enforcement authorities to take into account the fact that the decision in question had been the subject of an appeal before considering enforcement action. However, this is merely an argument made to the Board of Appeal and there is no guarantee that this has been made known to the enforcement authorities of the Member States. Thus, the Appellant is not sufficiently protected against the risk that a Member State will apply the original deadline in the Contested Decision. Indeed since enforcement action is, in accordance with Article 126 of the REACH Regulation, the competence of the Member States, the Agency cannot know for certain how those Member States would act. In this respect, there is a risk that the Agency's narrow interpretation of suspensive effect would infringe the requirements of legal certainty.

124. Consequently, the Appellant shall submit the information required by the Contested Decision within 24 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. **Rejects the claim for the reimbursement of costs incurred by the Appellant in the appeal proceedings.**
4. **Decides that the Appellant shall submit the information required by the Agency's Decision CCH-D-0000002044-86-04/F of 5 April 2012 within 24 months from the date of notification of the Board of Appeal's decision in this case.**

Andrew FASEY
On behalf of the Chairman of the Board of Appeal pursuant to
Article 3(5) of the Rules of Procedure

Sari HAUKKA
Registrar of the Board of Appeal