EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

1 August 2013

(*Compliance check of a registration – Dossier updates submitted during the decision-making process – Legal certainty*)

Case number	A-003-2012
Language of the case	English
Appellant	THOR GmbH Germany
Representative	Mr Martin Ahlhaus Noerr LLP München Germany
Contested decision	CCH-D-0000001752-76-06/F of 28 February 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 and Rapporteur), Andrew FASEY (Technically Qualified Member) and Rafael Antonio LÓPEZ PARADA (Legally Qualified Member)

Registrar: Sari HAUKKA

gives the following

Decision

RELEVANT LEGISLATION

1. Article 22(2) of the REACH Regulation provides:

'*A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 40, 41 or 46 or take into account a decision made in accordance with Articles 60 and 73, within the deadline specified in that decision. The Agency shall notify the competent authority of the relevant Member State that the information is available on its database*.'

2. Article 41(1) to (4) of the REACH Regulation provides:

'Compliance check of registrations
1. The Agency may examine any registration in order to verify any of the following:
(a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;
(b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;
(c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;
(d) that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.

2. The list of dossiers being checked for compliance by the Agency shall be made available to Member States competent authorities.

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.

4. The registrant shall submit the information required to the Agency by the deadline set.'

3. Article 42 of the REACH Regulation provides:

'Check of information submitted and follow-up to dossier evaluation
1. The Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary.

2. Once the dossier evaluation is completed, the Agency shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. The competent authorities shall use the information obtained from this evaluation for the purposes of Article 45(5), Article 59(3) and Article 69(4). The Agency shall use the information obtained from this evaluation for the purposes of Article 44.'

4. Articles 50(1) of the REACH Regulation provides:

'Registrants' and downstream users' rights
1. The Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay.
The competent authority (for decisions taken under Article 46) and the Agency (for decisions taken under Articles 40 and 41) shall take any comments received into account and may amend the draft decision accordingly.'

5. Article 51 of the REACH Regulation provides:

'Adoption of decisions under dossier evaluation
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).

8. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 3 and 6 of this Article.'

6. Article 92(2) of the REACH Regulation provides:

'The appeal, together with the statements of the grounds thereof, shall be filed in writing to the Agency within three months of the notification of the decision to the person concerned, or in the absence thereof, of the day on which it became known to the latter, unless otherwise provided in this Regulation.'

7. Article 10 of the European Code of Good Administrative Behaviour provides:

'Legitimate expectations, consistency, and advice
1. The official shall be consistent in his or her own administrative behaviour as well as with the administrative action of the Institution. The official shall follow the Institution's normal administrative practices, unless there are legitimate grounds for

departing from those practices in an individual case. Where such grounds exist, they shall be recorded in writing.

2. The official shall respect the legitimate and reasonable expectations that members of the public have in the light of how the Institution has acted in the past.

3. The official shall, where necessary, advise the public on how a matter which comes within his or her remit is to be pursued and how to proceed in dealing with the matter.'

SUMMARY OF THE FACTS

Background to the dispute

8. On 21 October 2010, the Agency initiated a compliance check of the Appellant's registration dossier for an organic nitrogen-phosphorous compound (hereinafter the 'registered substance') following a tonnage band update which had been submitted on 23 September 2010.

9. On 14 July 2011, following the compliance check, the Agency notified the draft decision to the Appellant and invited it to provide comments within 30 days of receipt of the draft decision. The draft decision included the following information requirements:

   - Skin sensitisation – Local lymph node assay (hereinafter referred to as 'skin sensitisation - LLNA'); a robust study summary in the IUCLID format containing information concerning the choice of dose levels used in the study, information about the results of the use of positive controls either in the study itself, or relevant historical data which validates the reliability of the study;
   - Sub-chronic toxicity study (90-day) (Section 8.6.2 of Annex IX to the REACH Regulation), rodents, by the oral route (EU test method B.26) to be performed with the registered substance; and
   - Pre-natal developmental toxicity study (Section 8.7.2 of Annex IX to the REACH Regulation), one species, by the oral route (EU test method B.31) to be performed with the registered substance.

10. On 14 July 2011, the Agency also sent a quality observation letter to the Appellant identifying certain additional deficiencies in the dossier related to acute toxicity testing by inhalation, reproductive toxicity and risk characterisation.

11. On 9 August 2011, a telephone conference took place between the Agency and the Appellant to discuss the quality observation letter and certain aspects of the draft decision (hereinafter the 'telephone conference').

12. On 16 August 2011, the Appellant provided comments on the three endpoints addressed in the draft decision. The final conclusions of the draft decision were not however amended by the Agency as a result of these comments.

13. On 2 September 2011, the Agency notified the Member State Competent Authorities (hereinafter 'MSCAs' or 'MSCA' if singular) of the draft decision and invited them to submit proposals for amendments within 30 days. Following the receipt of a proposal for amendment from one MSCA the Agency amended the draft decision to include an additional information requirement for a reproductive toxicity screening study (OECD Test Guideline 421).

14. On 5 October 2011, the Agency notified the Appellant of the proposal for amendment and invited it to provide comments on the proposal within 30 days of the receipt of that notification.

15. On 17 October 2011, the draft decision was referred to the Member State Committee (hereinafter the 'MSC').

16. On 4 November 2011, the Registrant provided comments on the proposal for amendment. On the same date, the Appellant also updated its registration dossier (hereinafter the 'updated registration dossier') to include information concerning skin sensitisation - LLNA and an exposure-based waiving strategy covering the requested studies.

17. At the MSC meeting, which took place between 7 and 9 December 2011, the MSC further amended the draft decision and a unanimous agreement of the MSC was reached on 8 December 2011.

18. On 28 February 2012, the Agency adopted the Contested Decision which requests the Appellant to provide, in the IUCLID format, a robust study summary on the following endpoint:

    - Skin sensitisation - LLNA (Section 8.3 of Annex VII to the REACH Regulation): Information concerning the choice of dose levels used in the study, information about the results of the use of positive controls either in the study itself, or relevant historical data which validates the reliability of the study.

    The Contested Decision also requests the Appellant to submit the following information using the test methods indicated:

    - Sub-chronic toxicity study (90-day) (Section 8.6.2 of Annex IX to the REACH Regulation), rodents, by the oral route (EU test method B.26);
    - Screening for reproductive/developmental toxicity, one species (Section 8.7.1 of Annex VIII to the REACH Regulation) (OECD test guideline 421);
    - Pre-natal developmental toxicity study (Section 8.7.2 of Annex IX to the REACH Regulation), one species, by the oral route (EU test method B.31).

19. According to the cover letter accompanying the Contested Decision, the information contained in the updated registration dossier was not taken into account by the Agency for the purposes of the Contested Decision on the grounds that the decision-making process was at its final stages at the time the update was submitted.

Procedure before the Board of Appeal

20. On 25 May 2012, the Appellant lodged an appeal at the Registry of the Board of Appeal in which it requested the Board of Appeal to order the Agency to use the Appellant's updated registration dossier as the basis for its final decision (hereinafter 'the Appellant's first submission'). On 29 May 2012, the Appellant's first submission was served on the Agency.

21. On 6 June 2012, the Appellant was invited by the Registry to clarify the scope of a confidentiality request contained in its Notice of Appeal, to provide a proof of authority to act and to clarify whether it contested the Contested Decision in its entirety.

22. On 20 June 2012, the Appellant, through a newly appointed representative, informed the Board of Appeal, inter alia, that it was contesting the Contested Decision in its entirety (hereinafter the 'Appellant's second submission'). Furthermore, in that submission the Appellant stated that it requested the Board of Appeal to revoke or annul the Contested Decision or order the Agency to act to that effect and order the Agency to refund the appeal fee. The Appellant also set out further arguments in support of its appeal.

23. On 4 July 2012, the Chairman adopted a decision accepting the Appellant's request for confidential treatment of the chemical substance name, the CAS number and the registration number.

24. On 5 September 2012, the Board of Appeal adopted a decision rejecting an application to intervene on the grounds that the Applicant had not established an interest in the result of the case as required by Article 8(1) 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').

25. On 27 August 2012, the Agency submitted its Defence. On 28 September 2012, the Appellant submitted observations on the Defence which contained inter alia a request to stay proceedings whilst its updated registration dossier is examined in accordance with Article 42(1) of the REACH Regulation by either the Board of Appeal or the Agency.

26. On 24 October 2012, the Registry requested observations from the Agency on the Appellant's request to stay proceedings. By letter lodged at the Registry on 13 November 2012, the Agency opposed the request to stay proceedings. On 27 November 2012, the Board of Appeal adopted a decision rejecting the request to stay proceedings on the grounds that granting the request would in effect be equivalent to deciding on certain of the issues under consideration in the appeal proceedings themselves.

27. On 5 December 2012, the parties were notified that the Board of Appeal had decided to close the written procedure.

28. On 11 December 2012, the Agency responded that it did not request an oral hearing. On 19 December 2012, the Appellant informed the Registry that, in accordance with Article 13(1) of the Rules of Procedure, it requested an oral hearing to be held. The Appellant's request for a hearing also contained a request for a change of the language of the case from English to German during the hearing.

29. On 21 December 2012, the Registry of the Board of Appeal invited the Agency to submit its observations on the Appellant's request to use German during the oral hearing. By letter lodged at the Registry on 17 January 2013, the Agency opposed the Appellant's request. On 8 February 2013, the Board of Appeal adopted a decision dismissing the Appellant's request to use German during the oral hearing.

30. On 23 April 2013, an oral hearing took place by video-conference at which the parties presented oral arguments and their answers to questions put to them by the Board of Appeal. In particular, the parties were heard concerning the time limit for updating dossiers which are the subject of compliance checks and the procedure related to Article 42(1) of the REACH Regulation.

ARGUMENTS OF THE PARTIES

Appellant's arguments

31. In its first submission the Appellant requests the Board of Appeal to order the Agency to use the Appellant's updated registration dossier as the basis for its final decision as it has proposed an exposure-based waiving strategy in the updated registration dossier to meet certain information requirements in the Contested Decision. The Appellant concludes that it needs an evaluation of this waiving strategy in order to be able to decide on whether to initiate the studies requested in the Contested Decision.

32. The Appellant states that, although it had been informed by the Agency that an update of the registration dossier is possible at any time during the decision-making process, its update had not been taken into account by the Agency on the grounds that the decision-making process was at its final stages at the time the update was received. The Appellant claims that the Contested Decision was therefore adopted on the basis of an old and obsolete version of its registration dossier, namely that of 23

September 2010, and that it does not know if and how its registration dossier update would have affected the Contested Decision.

33. In its second submission, the Appellant confirmed that it was challenging the Contested Decision in its entirety. The Appellant also stated that it requested the Board of Appeal to annul the Contested Decision or order the Agency to act to that effect and order the Agency to refund the appeal fee.

34. In its second submission, the Appellant also included a number of comments regarding the adequacy of the data submitted in its updated registration dossier. The Appellant also supported its appeal with the following arguments:

(a) In failing to take into account the updated registration dossier the Agency had breached Article 41 of the REACH Regulation which requires the Agency to examine whether all the required information is included in the dossier. As the registration dossier is the subject of the compliance check, all updates must be taken into account;

(b) Articles 50 and 51 of the REACH Regulation do not require the Agency to continue with the decision-making process without considering dossier updates;

(c) If the Agency had acted legally in not taking into account the updated registration dossier, it should have pursuant to Article 42(1) of the REACH Regulation, revoked the Contested Decision once it received the update. The Appellant claims that the repeal of the Contested Decision is necessary to ensure that the risk of enforcement action is avoided;

(d) The Appellant updated its dossier on 4 November 2011 in response to the Agency's invitation pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment of the draft decision.

35. In its observations on the Agency's Defence the Appellant also raised arguments related to the breach of the principle of proportionality and the violation of Article 10(2) and (3) of the European Code of Good Administrative Behaviour.

Agency's Defence

36. In its Defence the Agency presents a number of arguments related to the admissibility of the appeal as well as the substance of the case.

37. The Agency's admissibility arguments can be summarised as follows:

(a) The order sought in the Appellant's first submission is inadmissible as it is not seeking the annulment of the Contested Decision. Furthermore, the Appellant has no interest in seeking an order requiring the Agency to adopt a new decision as the Agency is already required by Article 42(1) of the REACH Regulation to examine whether the information provided in the updated registration dossier complies with the Contested Decision. The order sought in the Appellant's second submission is also inadmissible as it was lodged after the expiry of the time limit for lodging an appeal set out in Article 92(2) of the REACH Regulation and is different from the order sought in the first submission. Consequently, the appeal as a whole must be dismissed as inadmissible;

(b) The pleas in law raised for the first time in the Appellant's second submission are inadmissible because they were submitted after the expiry of the time limit set for lodging an appeal. In particular, the Agency considers that the arguments regarding the inclusion of an updated robust study summary concerning the endpoint for skin sensitisation in the updated registration dossier should be dismissed as inadmissible. For the same reasons, the Agency also considers that the arguments based on Articles 41, 50 and 51 of the REACH Regulation should be dismissed as inadmissible.

38. The Agency also claims that the appeal is unfounded and its arguments in this respect can be summarised as follows:

    (a) The Agency will examine the updated registration dossier under Article 42(1) of the REACH Regulation after the deadline in the Contested Decision has expired; if the Appellant is convinced that the information submitted in the update complies with the Contested Decision, it will not need to submit any further information for the relevant endpoints;

    (b) The Agency is not bound to examine dossier updates once the decision-making process under Article 51 of the REACH Regulation has started. Article 51 contains strict deadlines which cannot be put on hold once the draft decision has been sent to the MSCAs. The Agency has no obligation under Articles 22, 41, 42, 50 or 51 of the REACH Regulation to evaluate updated information submitted in the course of the decision-making process. If this were not the case, the efficiency of the decision-making process would be seriously undermined;

    (c) At the telephone conference only an update of the registration dossier with respect to skin sensitisation - LLNA was discussed. In any case, the telephone conference was only an informal discussion and the minutes thereof, which are not signed, contain a disclaimer that they do not constitute formal advice;

    (d) There is sufficient guidance available, in particular 'Practical Guide 12: How to communicate with ECHA in dossier evaluation' (published on 31 January 2011; hereinafter 'Practical Guide 12'), to make it clear that the Agency would not take into account in its evaluation decision-making process any updates received after the draft decision has been communicated to the MSCAs for proposals for amendments;

    (e) Whilst Article 42(1) of the REACH Regulation requires the Agency to examine information submitted in the updated registration dossier to see if this complies with the Contested Decision this does not mean that the Agency has to withdraw the Contested Decision or adopt a new decision as a result of that update.

REASONS

Admissibility of the appeal

39. The Board of Appeal will firstly examine the Agency's arguments concerning the admissibility of the appeal.

Admissibility of the appeal in its entirety

40. The Agency claims that in its first submission the Appellant did not seek the annulment of the Contested Decision but rather requested the Board of Appeal to order the Agency to examine the updated registration dossier and take a decision on the basis of that information. The Agency claims that it is only in the Appellant's second submission that the Appellant sought the annulment of the Contested Decision.

41. The Agency claims further that the Appellant's second submission, including the order seeking the annulment of the Contested Decision, must be dismissed as inadmissible as that submission was received outside the time limit for lodging an appeal set in Article 92(2) of the REACH Regulation.

42. The Agency claims in addition that the order sought in the Appellant's second submission is different from that contained in its first submission and that the Appellant cannot modify the form of order sought after the expiry of the time limit set for lodging an appeal.

43. The Agency continues that if the Board of Appeal decides that the Appellant's second submission is inadmissible, the appeal as set out in the first submission is also inadmissible as it is not clearly appealing against the Contested Decision and the Board of Appeal is only competent to hear appeals against Agency decisions.

44. In its observations on the Defence, the Appellant claims that it is clear from its first submission that it was seeking the annulment of the Contested Decision and that the second submission only clarified that fact. The Appellant adds that an appeal must be construed according to the circumstances of a particular case and thus it is irrelevant that the Appellant did not expressly use the word 'annulment' or 'revocation' in its first submission. According to the Appellant, appeals must be construed in accordance with the Appellant's objective rather than by simply looking at the specific wording used.

45. The Board of Appeal considers that where the Appellant has not explicitly set out the remedy sought it may nonetheless be possible to infer a particular form of order sought from the wording of the Notice of Appeal read as a whole (see by analogy, for example, the Order of the Court of 7 February 1994 in Case C-388/93 *PIA HiFi v Commission*, [1994] ECR I-387, paragraph 10 and the Order of the Sixth Chamber of the General Court of 13 April 2011 in Case T-320/09 *Planet AE v Commission*, [2011] ECR II-1673, paragraph 23).

46. In the present case the Board of Appeal finds that it can be readily implied from the Appellant's first submission that the Appellant is seeking, inter alia, the annulment of the Contested Decision on the grounds that the Agency did not take account of the updated registration dossier. In particular, the Appellant states in its first submission that the Board of Appeal should request the Agency '… to use our updated registration dossier dated 4 November 2011 as the basis for the final decision' and '… we request a prompt review and re-evaluation of our updated registration dossier as the basis for the final decision'. The Board of Appeal considers that the Appellant clearly requests that its updated registration dossier, rather than its registration dossier of 23 September 2010, is considered for the purposes of the final decision. The Appellant is therefore requesting that the Contested Decision is annulled and replaced by a decision which takes into consideration the updated registration dossier. The Appellant's second submission makes the request more explicit.

47. The Agency's claim that the appeal is inadmissible in its entirety on the grounds that it does not seek the annulment of the Contested Decision must therefore be dismissed as unfounded.

48. Since the Board of Appeal has found that it can be readily implied from the Appellant's first submission that the Appellant sought inter alia the annulment of the Contested Decision, the Agency's claim that the Appellant amended the remedy sought during the proceedings must also be dismissed.

Appellant's alleged lack of interest in seeking a decision of the Board of Appeal

49. The Agency claims that the appeal is inadmissible on the grounds that the Appellant does not have an interest in pursuing the appeal as it would not derive any benefit from a Board of Appeal decision. The Agency considers this to be the case as it will examine the updated registration dossier pursuant to Article 42(1) of the REACH Regulation after the expiry of the deadline set in the Contested Decision. The Agency also stated during the proceedings that if the information contained in the updated registration dossier, including the waiving strategy, complies with the Contested Decision, the Appellant will not need to submit any further information.

50. In assessing whether the Appellant has an interest in pursuing its appeal, the Board of Appeal observes that there are considerable differences between the potential consequences of the procedures foreseen under Articles 41 and 42 of the REACH Regulation respectively.

51. In particular, under Article 41 of the REACH Regulation, if the Agency observes that the registration dossier does not comply with the information requirements set out in the REACH Regulation the Appellant is provided a specified period of time to provide the missing information before the dossier is re-evaluated under Article 42 of the REACH Regulation. Consequently, in the present case, if the Appellant's waiving strategy is examined under Article 41 and found not to meet the requirements of the REACH Regulation, the Appellant will be given a deadline by which it must put its dossier in order. Enforcement action by a Member State cannot follow an Agency decision adopted under Article 41 of the REACH Regulation. However, enforcement action can potentially follow if an evaluation by the Agency under Article 42 of the REACH Regulation reveals that the updated registration dossier does not comply with the Agency's decision adopted under Article 41.

52. During the oral hearing the Agency briefly set out the procedure that it follows under Article 42 of the REACH Regulation (hereinafter the 'Article 42 procedure'). The Agency explained firstly that the Article 42 procedure is initiated by the Agency after the deadline set in the final decision, pursuant to Article 41 of the REACH Regulation, has expired. The Agency then explained that it has identified four basic scenarios:

    (i) If the registrant updates its dossier in a manner which complies with the information required in the Agency's final decision, an Article 42(2) notification is sent to the MSCA concerned and the European Commission informing them of this fact;

    (ii) If no update is received or the update is inadequate a notification of this fact is sent to the MSCA concerned, the European Commission and the registrant. This statement of non-compliance sets out the reasons for the non-compliance with the Agency's decision;

    (iii) If the registrant complies with the Agency's final decision but other concerns regarding the same endpoint are identified by the Agency, the Agency may issue a new decision under Article 42(1) of the REACH Regulation;

    (iv) If an update is received which complies with the Agency's decision but a new concern with other endpoints is identified as a result of the information received the Agency may open a new compliance check procedure on the basis of Article 41 of the REACH Regulation.

53. The Board of Appeal considers that the second scenario is of particular relevance for the present appeal as the Appellant is attempting to rely on an exposure-based waiving strategy rather than conducting the studies specifically requested in the Contested Decision.

54. Furthermore, before a decision is adopted under Article 41 of the REACH Regulation, pursuant to Articles 50 and 51 of the REACH Regulation, the registrant is given the opportunity to comment on the draft decision which is also subject to the scrutiny of the MSCAs and the MSC. However, it was stated by the Agency at the oral hearing that when it evaluates a registration dossier under Article 42 of the REACH Regulation it does not employ the procedures foreseen under Articles 50 and 51 except where new concerns are identified from the information provided by the registrant; in other words, the Article 42 procedure, as explained by the Agency, is completed by the Agency with no involvement of the registrant, the MSCAs or the MSC. In addition, the Agency stated at the hearing that the end result of the Article 42 procedure is not a formal Agency decision but rather an Agency opinion which is sent to the national enforcement authorities for potential follow-up action.

55. Consequently, in the present case, and in light of the Agency's description of the procedure it follows to implement Article 42 of the REACH Regulation, if the Appellant submits its exposure-based waiving strategy in response to the Contested Decision and the Agency considers that this is insufficient to meet the concerns set out in the Contested Decision the Agency will send an opinion to that effect inter alia to the

MSCA concerned. According to the Agency, in these circumstances it will not permit the Appellant another opportunity to remedy the deficiencies identified by the Agency before its findings are sent to the MSCA.

56. The Board of Appeal observes therefore that, in practice, under the Article 42 procedure as explained by the Agency, the Appellant would be taking a significant risk if it does not carry out the requested studies to provide the information requested in the Contested Decision as the Agency may reject the exposure-based waiving strategy and such a rejection could result in enforcement action being taken against it.

57. The differences in consequences between the Article 41 procedure and Article 42 procedure followed by the Agency is further highlighted in the Agency's Defence where it is stated that '… if the update deviates from the actual information requested in the Contested Decision … [the Agency] may in its follow-up come to the conclusion that the updated information does not comply with the final decision and the information requirement is not fulfilled. In such circumstances [the Agency] would inform the relevant [MSCA] to draw the necessary consequences under national law of the registrant's failure to comply with [the Agency's] final decision'.

58. Following the Agency's explanation of the Article 42 procedure at the oral hearing, and without examining whether this explanation is correct, the Board of Appeal considers that, in particular due to the finality of the outcome of the Article 42 procedure, as well as the lack of involvement of registrants in the procedure leading to the adoption of Agency opinions, registrants clearly have an interest in having their registration dossiers examined under Article 41 rather than Article 42 of the REACH Regulation. The Agency's argument that the Appellant would not benefit from a decision of the Board of Appeal ordering the Agency to examine the updated registration dossier for the purposes of its final decision adopted pursuant to Article 41 of the REACH Regulation must therefore be dismissed as unfounded.

Alleged inadmissibility of the Appellant's arguments concerning skin sensitisation - LLNA

59. The Agency claims that the Appellant's arguments regarding the inclusion in the updated registration dossier of a robust study summary concerning the endpoint for skin sensitisation - LLNA should be dismissed as inadmissible as they were made for the first time in the Appellant's second submission and therefore were received outside the time limit for lodging an appeal set in Article 92(2) of the REACH Regulation.

60. The Board of Appeal observes that in its first submission the Appellant requests the Agency to use its 'updated registration dossier … as the basis for the Agency's final decision'. Since the updated registration dossier includes information on the endpoint for skin sensitisation - LLNA it can be readily implied that, in its first submission, the Appellant contested this aspect of the Contested Decision.

61. In the interests of clarity, on 6 June 2012, the Appellant was invited by the Registry to clarify, inter alia, whether it challenged the Contested Decision in its entirety. In response to the Registry's request, the Appellant confirmed that it was challenging the Contested Decision in its entirety, including the Agency's request to provide, in the IUCLID format, a robust study summary on the endpoint for skin sensitisation - LLNA.

62. The Board of Appeal therefore considers that in its first submission the Appellant was challenging the Contested Decision in its entirety, including the information requirement related to skin sensitisation - LLNA. The Agency's inadmissibility claim must therefore be dismissed as unfounded.

Scope of the appeal

63. In its first submission the Appellant contests the Agency's decision not to take into account the updated registration dossier, which was filed before the adoption of the Contested Decision and contained an exposure-based waiving strategy and information on skin sensitisation - LLNA. In that first submission the Appellant requests the Board of Appeal to order the Agency to evaluate, as a basis for the final decision, its updated registration dossier so that it will know whether its exposure-based waiving strategy is accepted and consequently whether it is obliged to conduct the specific studies requested by the Agency in the Contested Decision. In its first submission the Appellant does not contest the requested studies as such but rather the legality of the administrative practice which lead to the dossier update not being taken into account.

64. In its second submission, and later in the proceedings, however, the Appellant presented arguments regarding the adequacy of the data submitted in the updated registration dossier to meet the requirements of the REACH Regulation.

65. The Board of Appeal observes that the Appellant cannot modify the nature of the proceedings by amending the remedies sought after the deadline for submitting an appeal (see by analogy, for example, Case C-508/03 *Commission v United Kingdom*, [2006] ECR I-3969, paragraphs 60 to 65). Since the second submission was received outside the time limit for lodging an appeal set in Article 92(2) of the REACH Regulation, the Appellant's arguments related to the adequacy of the data contained in the updated registration dossier to meet the requirements of the REACH Regulation amount to an extension of the subject matter of the appeal.

66. Consequently, for the purposes of the present case, the Board of Appeal is not required to consider the adequacy of the information contained in the updated registration dossier to meet the requirements of the REACH Regulation or whether the information should have been requested by the Agency in the Contested Decision.

Claims under examination

Appellant's plea concerning the information provided by the Agency on the timing of dossier updates

67. The Board of Appeal will firstly consider the Appellant's plea that the Agency had lead it to believe that updates made at any time before the adoption of the Contested Decision would be taken into consideration therein.

Arguments of the parties

68. It is uncontested that the updated registration dossier submitted by the Appellant on 4 November 2011 was not taken into consideration for the purposes of the Contested Decision. The Agency's reasons for this are set out for example in the cover letter accompanying the Contested Decision which states that '… on 4 November 2011, [the Agency] has received a spontaneous update of the dossier. Unfortunately, as the decision-making process was at its final stages, the information contained in that update could not be taken into account in the present decision'. From other submissions made during the present proceedings it is clear that once a draft decision has been sent to the MSCAs for their comments and proposed amendments, any changes made to the registration dossier will not be taken into account by the Agency in the decision-making process.

69. The Appellant claims, however, that it had been informed by the Agency that an update of the registration dossier is possible at any time during the decision-making process. The Appellant claims that on the basis of the Agency's assurances it updated its dossier on 4 November 2011 assuming that the update would be taken into consideration in the Contested Decision.

70. The Appellant claims that during the telephone conference it had asked the Agency about the timing of an IUCLID update and was informed that an update can be made at any time in the procedure. In support of its claim the Appellant provided the minutes of the telephone conference which had been drawn up by the Agency. An examination of those minutes shows that the relevant section for the purposes of the Appellant's arguments reads as follows:

'… [the Agency] would like to inform the Registrant that in case of submission of an update of IUCLID dossier containing relevant information on Skin sensitisation – [LLNA], it may be considered to withdraw this point from the draft Decision if the update is received in the course of the Decision making process'.

71. The Appellant states in its observations on the Defence that those minutes do not include any statement that an update will not be taken into account after a certain stage of the decision-making process.

72. The Agency claims however that the telephone conference could not have created any legitimate expectations on the part of the Appellant that the updated registration dossier would be taken into consideration as part of the decision-making process. The Agency also states in its Defence that, with the exception of the information requirement for skin sensitisation – LLNA, the issues discussed during the telephone conference concerned issues presented in the Agency's quality observation letter only. According to the Agency, the quality observation letter is not a binding formal decision and does not fall within the decision-making process foreseen in Articles 50 and 51 of the REACH Regulation; it is rather a tool designed to help registrants improve their dossiers.

73. With regards to the statement in the minutes of the telephone conference (see paragraph 70 above), the Agency claims in its Defence that the Agency and the Appellant only discussed an update with respect to skin sensitisation - LLNA. The Agency claims that, unlike the updates related to the other information requested, that information requirement was only a matter of preparing and submitting the robust study summary of a study that the Appellant had already performed. The update could therefore be performed quickly. The Agency claims that, in contrast, updates concerning the other endpoints could not be made quickly. The Agency considers therefore that the Appellant could only have understood the statement in the minutes to refer to skin sensitisation - LLNA and not the other endpoints.

74. The Agency claims further that the wording of the minutes is vague and cannot be perceived to constitute a commitment by the Agency that it would consider any updates during the decision-making process. The Agency also points to the informal nature of telephone conferences and a disclaimer contained in the minutes specifying inter alia that statements made during telephone conferences cannot be considered as a formal opinion, position or advice from the Agency.

75. The Agency also claims that, in any case, sufficient guidance and instructions were available to the Appellant that should have made it clear that the Agency would not take into account in its evaluation decision any updates received after a draft decision has been communicated to the MSCAs for proposals for amendments. In this respect, the Agency refers in particular to Practical Guide 12.

76. The Agency also stated at the oral hearing that the cover letter accompanying the draft decision sent to the Appellant clearly set out the decision-making process and did not indicate that updates will be taken into account after the decision has been sent to the MSCAs. The Agency also stated that any misunderstanding held by the Appellant regarding the deadline to update its dossier for the purposes of the decision-making process must have been dispelled at the very latest on 5 October 2011 when the Appellant was given the opportunity to provide observations on the MSCA proposal for amendments. The Agency claims that it was clear from that letter that comments were expected only on the proposal for amendment.

77. The Agency also confirmed in its Defence that, in accordance with Article 22(1) of the REACH Regulation, registrants must on their own initiative update their registration dossiers without delay with relevant information. However, the Agency states that this requirement is unrelated to the issue of whether such updates should be taken into account in an on-going decision-making process.

Findings of the Board of Appeal

78. The Board of Appeal firstly observes that the rule that updates will not be taken into account in the decision-making process under Article 41 of the REACH Regulation after the draft decision has been notified to the MSCAs is not specifically foreseen in the REACH Regulation. This aspect of the decision-making process has been established by the Agency. Consequently, in the present case, for the Appellant to have known precisely the scope of its obligations with regards to the decision-making process, it not only had to know the relevant provisions of the REACH Regulation but also the Agency's practice in implementing them.

79. In its various submissions the Appellant claims that, at the time it submitted its updated registration dossier, it was not aware that an update filed after the draft decision had been sent to the MSCA would not be taken into account for the purposes of the decision-making process. The Appellant claims that the consequence of this was that it assumed its updated registration dossier would be taken into account for the purposes of the Agency's final decision on the registration dossier. It therefore falls on the Board of Appeal to consider whether the Appellant's understanding regarding its obligations in this regard was legitimate. The Board of Appeal will therefore examine whether a diligent and prudent registrant, exercising a reasonable level of due care, should have been aware of the deadline for making updates to ensure that those updates would be taken into account in the decision-making process.

80. The Board of Appeal observes that whilst it is the responsibility of all registrants to know the obligations applicable to them, the principle of legal certainty requires that every measure creating such obligations must be clear and precise and must be clearly brought to the notice of those concerned (see by analogy, for example, Case T-115/94 *Opel Austria v Council,* [1997] ECR II-39, paragraph 124 and Case C-17/01 *Finanzamt Sulingen v Walter Sudholz,* [2004] ECR I-4243, paragraph 34). In the present case, particularly since the rule at issue is not contained in the REACH Regulation, the Agency was therefore obliged to clearly and precisely inform the Appellant in due time that updates received after the draft decision had been sent to the MSCAs would not be taken into account in the decision-making process.

81. The Board of Appeal considers that the obligation to clearly and precisely inform registrants of their obligations in due time is, in this instance, particularly important because of the differences in the implementation of the procedures under Articles 41 and 42 of the REACH Regulation, as set out in paragraphs 49 to 58 of this Decision, and the different potential consequences of decisions taken under those Articles. In particular, according to the Agency's implementation of Article 42, as explained at the oral hearing, a registrant is not granted the opportunity to comment on an Agency opinion made pursuant to Article 42 and no additional time is permitted to comply with the opinion before it is sent to the Member State enforcement authorities ahead of any possible enforcement action.

82. In examining whether the Appellant was clearly and precisely informed of its obligations by the Agency in due time the Board of Appeal will firstly examine whether the Appellant was specifically and individually informed by the Agency of the deadline for making updates to be considered in the decision-making process.

83. The Board of Appeal considers that the Parties' submissions in this case show that the Agency specifically and individually informed the Appellant of this rule firstly in an email of 15 February 2012 regarding the draft minutes of the MSC meeting and, later,

in the cover letter accompanying the Contested Decision. Those communications made it explicit that updates received after the draft decision had been sent to the MSCAs would not be taken into account in the decision-making process. The Board of Appeal considers, however, that since those communications were made to the Appellant after the draft decision had been sent to the MSCAs and after the update had been made they cannot be considered as being sufficient to inform the Appellant of the rule at issue in due time.

84. The Agency claimed at the oral hearing that the letter of 5 October 2011, in which the Appellant was given the opportunity to provide observations on the MSCA's proposal for amendments, made it clear that updates to be considered in the decision-making process could not be made after the draft decision had been referred to the MSCAs. This claim cannot, however, be accepted as that letter contained no clear reference to the deadline for updated dossiers to be taken into consideration in the decision-making process. Furthermore, that letter was received only after the draft decision had been submitted to the MSCAs and therefore after the deadline for submitting updates imposed by the Agency. In addition, the Board of Appeal also considers that, from the various submissions in the case, there is no evidence that the Appellant was specifically informed at the telephone conference that an update had to be made before the draft decision was referred to the MSCAs in order for it to be taken into account in the decision-making process.

85. The Board of Appeal also considers that the Agency could, without creating an unreasonable administrative burden, individually inform the addressees of draft decisions that updates received after the draft decision has been sent to the MSCAs will not be taken into account in the decision-making process. For example, wording to this effect could be inserted in the cover letters accompanying the draft decision sent to registrants for their comments. Concretely, in the present case, the Appellant could have been informed in writing by the Agency when it was notified of the draft decision for the first time on 14 July 2011 and where the main parts of the procedure to be followed in the decision-making process were set out.

86. The Board of Appeal also considers that it is pertinent in the present case that on 16 August 2011, before the draft decision was sent to the MSCAs on 2 September 2011, the Appellant informed the Agency that it intended to update its dossier, at least with regards to the 90-day sub-chronic toxicity study, in response to the concerns set out in the draft decision. In its comments on that information requirement submitted via REACH-IT, and included as an annex to the Notice of Appeal and the Defence, the Appellant, having mentioned that it still supported its exposure-based waiving strategy for this study, stated inter alia that '… Thor does not see any reason to conduct this additional study. These justification arguments will be added to the IUCLID in the Endpoint summary of repeated dose toxicity under discussion'. It is also clear that an update of the dossier was also discussed, at least with respect to skin sensitisation – LLNA, at the telephone conference.

87. The Board of Appeal considers that, since the Appellant had informed the Agency of its intention to update its dossier, the latter was under an even greater responsibility to inform the Appellant that updates would not be taken into consideration after the dossier had been sent to the MSCAs.

88. In addition, the Board of Appeal notes that as part of its Defence the Agency submitted the 'Working Procedure for the MSC to process draft decisions under dossier evaluation' (updated version of 2 February 2011; hereinafter the 'Working Procedure'). It is stated on page 2 of that document that the REACH Regulation does not specify any deadline for the Agency to take into account the registrant's comments on the draft decision and continue the process. Footnote 2 on page 3 of that document states further that '[t]he Agency foresees normally a minimum period of 15 days to process the comments of the registrant(s)/downstream user(s) and to prepare and submit the (modified) draft decision to the MSCAs. Beyond these 15 days, the date of

notification of the MSCAs shall be adjusted to the dates of the MSC-meetings'. The Board of Appeal considers that it is clear that the decision-making process should not be unreasonably delayed by unrealistic or vague assurances that a registration dossier will be updated. Nonetheless, the Board of Appeal considers that in the present case, as the Appellant had indicated its intention to update its dossier to take into account the Agency's concerns as set out in the draft decision, the Agency should have seriously considered whether it was appropriate to delay the sending of the draft decision to the MSCAs to give the Appellant the opportunity to update its dossier. In the present case the Appellant notified the Agency of its intention to update the dossier on 16 August 2011 and the Agency notified the draft decision to the MSCAs on 2 September 2011. This permitted the Appellant only a short period of time, which was only marginally over the minimum time referred to in the Working Procedure, in which to update its dossier.

89. For the reasons given above, the Board of Appeal therefore finds that the Appellant was not specifically and individually informed in due time by the Agency of the deadline for making updates to be considered in the decision-making process. The Board of Appeal will next address the Agency's arguments that the Appellant should have nonetheless been aware that its dossier update would not be taken into consideration as sufficient guidance is available on that rule.

90. In support of its arguments that sufficient guidance existed on this point the Agency refers to the following paragraphs from page 17 of Practical Guide 12:

'Once ECHA has sent the initial draft decision to the registrant (via REACH-IT), the registrant has 30 days to provide comments via a webform. The deadline for the comments and the address of the webform are specified in the cover letter. In addition to commenting, the registrant may also during this time update the dossier with information relevant for filling the identified information gap (e.g. an improved justification for using adaptations to standard information requirements). If, after reviewing the registrant's comments and/or updated dossier, ECHA considers that the updated dossier meets the REACH requirements, the decision process is terminated and the examination closed.

[…]

The Committee will take the comments of the MSCA and registrant into account while deliberating the draft decision. The decision will always be made based on the data available in the registration dossier at the time of sending the draft decision to the Member States for proposing amendments and is without prejudice to updates made after this date. This is necessary to ensure a smooth decision-making process. Explanations or promises of the registrant without updates of the registration dossiers cannot be taken into account in the decision-making process. The commenting periods for the registrant are short, and it will be challenging to update a dossier or even to provide new scientific comments within 30 days. Thus ECHA recommends that registrants always include sufficient and the best possible justifications and information in the dossier first submitted to ECHA'.

91. The Agency also referred to the following paragraph from page 21 of Practical Guide 12:

'Registrants have the possibility to comment ECHA's draft decisions and/or to update their dossier during a 30 day commenting period. In fact registrants have the right to update their dossier at any time, but in order to impact on the evaluation process the deadlines must be respected'.

92. In addition, the Appellant and the Agency both refer in their submissions to the Procedure on Dossier Evaluation, which was authorised for publication on 28 March 2011. Section 8.2 of that document states:

'The dossier may be updated at any point by the registrant … The update of the dossier may lead to the procedure being terminated at any stage. Final decisions will be taken without prejudice to updates submitted by registrant after first referral of [the draft decision] to MSCAs for proposing amendments'.

93. The Board of Appeal firstly observes that Practical Guide 12, published on 31 January 2011, and the Procedure on Dossier Evaluation, authorised for publication on 28 March 2011, were available to the Appellant prior to the date it received the Agency's draft decision.

94. Furthermore, as stated above in paragraph 80 of the present decision, the Board of Appeal considers that it is the duty of every registrant to know the obligations imposed on them. However, according to the principle of legal certainty, rules should be clear and precise, so that individuals may be able to ascertain unequivocally what their rights and obligations are and may take steps accordingly (see by analogy for example Case C−110/03 *Belgium v Commission,* [2005] ECR I−2801, paragraph 30).

95. The Board of Appeal considers that when deciding whether the documents mentioned above are clear and precise the particular circumstances of the case must also be taken into consideration. In particular, as noted above, it should be taken into consideration that the Agency did not take any specific steps to draw the Appellant's attention to the fact that updates will not be taken into consideration for the purposes of the decision-making if they are received after the draft decision has been sent to the MSCAs; this failure to inform the Appellant occurred despite the fact that the Appellant had also made its intention to update the registration dossier known to the Agency.

96. Having regard to the above, the Board of Appeal finds that the wording of Practical Guide 12 and the Procedure on Dossier Evaluation on this issue is unclear and could lead to it being misconstrued. In particular, the use of the term 'without prejudice' in the following phrases, '… and is without prejudice to updates made after this date' and '[f]inal decisions will be taken without prejudice to updates submitted by registrant after first referral of [draft decision] to MSCAs …', could lead to the rule on the deadline for updates to be considered in the decision-making process being misunderstood by a diligent and prudent registrant.

97. The Board of Appeal further considers that the paragraph cited by the Agency from page 21 of Practical Guide 12 does not contain a clear reference to the fact that updates received after the draft decision has been sent to the MSCAs will not be taken into consideration in the decision-making process leading to the adoption of the Contested Decision.

98. In conclusion, the Board of Appeal finds that in the present case, in the absence of any mention in the REACH Regulation of a deadline for the submission of registration dossier updates in order for them to be considered in the decision-making process under Article 41 of the REACH Regulation, and the Agency's shortcomings in communicating in a clear, precise and timely manner both individually to the Appellant as well as more generally in the guidance meant that even a diligent and prudent registrant exercising a reasonable level of due care could have been mistaken in thinking that updates made at any time before the adoption of the Contested Decision would be taken into consideration in the decision-making process. This is in particular the case in the circumstances of the present appeal given the fact that the Appellant had informed the Agency of its intention to update the registration dossier in response to the draft decision.

99. The Board of Appeal therefore considers that in the present case the Agency has infringed the principle of legal certainty as the rule that registration dossier updates will not be taken into account for the purposes of the final decision if they are submitted after the draft decision has been sent to the MSCAs was not clear and precise nor did the Agency make that rule known to the Appellant in due time.

100. For these reasons, the Board of Appeal annuls the Contested Decision and remits the case to the competent body of the Agency for re-evaluation of the registration dossier as updated by the Appellant.

Other pleas raised by the Appellant

101. Since the Board of Appeal has found in favour of the Appellant the Board of Appeal does not consider it necessary to examine the additional pleas raised by the Appellant in support of its appeal or the Agency's arguments related to the admissibility of those pleas.

Refund of the appeal fee

102. 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.

103. As the Board of Appeal has decided the appeal in favour of the Appellant in the present case, the appeal fee shall be refunded on that basis.

ORDER

On those grounds,

THE BOARD OF APPEAL

hereby:

Annuls Decision CCH-D-0000001752-76-06/F adopted by the European Chemicals Agency on 28 February 2012.

Remits the case to the competent body of the Agency for re-evaluation of the registration dossier as updated by the Appellant.

Orders the refund of the appeal fee.

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal