

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

**03 December 2014**

*(Permission to proceed with registration – Registration deadline for phase-in substances – Data sharing dispute – Admissibility – Business rules check – Technical completeness check)*

|                             |   |
|-----------------------------|---|
| <b>Case number</b>          | A-005-2013  |
| <b>Language of the case</b> | English   |
| <b>Appellant</b>            | Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein<br>Austria   |
| <b>Representative</b>       | Darren Abrahams and Indiana de Seze<br>Steptoe & Johnson LLP<br>Brussels<br>Belgium   |
| <b>Intervener</b>           | FW Hempel Metallurgical GmbH<br>Germany   |
| <b>Representative</b>       | Scott Megregian, Vanessa Edwards and Raminta Dereskeviciute<br>K&L Gates LLP<br>London<br>United Kingdom  |
| <b>Contested Decision</b>   | DSH-30-3-0018-2013 of 8 May 2013 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 30(3) 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), Rafael Antonio LÓPEZ PARADA (Legally Qualified Member), and Andrew FASEY (Technically Qualified Member and Rapporteur)

Registrar: Sari HAUKKA

gives the following

## Decision

### SUMMARY OF THE FACTS

#### Background to the dispute

1. On 24 April 2013, FW Hempel Metallurgical GmbH, who is also the Intervener in the present proceedings (hereinafter the 'Data Claimant' or 'Intervener'), submitted a request to the Agency, pursuant to Article 30(3) of the REACH Regulation (all references to Articles hereinafter concern the REACH Regulation unless stated otherwise), to be given permission to refer to data involving testing on vertebrate animals contained in the joint registration dossier for vanadium in its registration of the same substance. This request followed an alleged failure of negotiations to agree on the costs to be paid by the Data Claimant to share that data. Pursuant to Article 23(2), the Data Claimant was required to submit a registration dossier for vanadium by 1 June 2013.
2. On 8 May 2013, the Agency sent a letter to the Appellant (hereinafter the 'Contested Decision') requesting it to provide information to the Agency to allow it to assess the efforts made to reach an agreement on the sharing of the data requested by the Data Claimant in accordance with Article 30 (hereinafter the 'data sharing dispute'). The letter was entitled 'Request for information relating to a data sharing dispute under Article 30(3) submitted to [the Agency] by [the Data Claimant]...'.  
  
3. In addition, the Contested Decision informed the Appellant that:  
*'Due to the short period between the complaint and the registration deadline of 31 May 2013 [the data sharing dispute] may not be concluded by that date. Therefore, in order to enable the [Data Claimant] to fulfil their legal registration obligations, [the Agency] can allow them to proceed with the registration without the full data set, while the data sharing dispute is being processed. However, you must note that this permission is only temporary and does not prejudice the final outcome of the contradictory assessment.'*
4. On 8 May 2013, the Agency also sent a letter to the Data Claimant. In that letter the Agency informed the Data Claimant, inter alia, that it had requested from the Appellant information on the negotiations that took place regarding the data sharing dispute. In that letter the Agency also described what it termed a 'contingency procedure' (hereinafter the 'Agency's contingency procedure') which it said it had established because 'due to the short period between [the] claim and [the] registration deadline of 31 May 2013' it may not have decided on the data sharing dispute by that date. The letter to the Data Claimant provides further:  
*'... in order to enable you to fulfil your legal registration obligations, [the Agency] can allow you to proceed with the registration without the full data set, while the data sharing dispute is being processed. However, you must note that this permission is only temporary and does not prejudice the final outcome of the contradictory assessment. This permission to proceed, being only temporary, may entail legal consequences should [the Agency] eventually decide not to grant [the Data Claimant] a definitive permission to refer to the studies submitted by the existing registrants ....  
  
Moreover, due to the dispute you will not be able to submit all the required information (as per Article 22(2)) and you will not pass the technical completeness check (TCC). Therefore, we are enclosing in Annex II instructions on how to submit your registration dossier in order to be given an extended reasonable deadline'.*

5. Annex I to the letter to the Data Claimant is entitled 'Possible legal consequences of the "contingency" data sharing dispute procedure' whilst Annex II provides further instructions on how to submit a registration dossier under the Agency's contingency procedure. In particular, the Agency provides instructions on how to complete the fields of the registration dossier that relate to the endpoints which are the subject of the data sharing dispute. In these instructions, amongst other things, the Agency informs the Data Claimant of a code that it should enter into the fields affected by the data sharing dispute. On 30 May 2013, the Data Claimant submitted its registration dossier for vanadium.
6. As far as it is relevant for the present appeal, in the final decision of 12 July 2013 on the data sharing dispute granting the Data Claimant permission to refer, which is the subject of separate appeal proceedings in Case A-017-2013, the Agency stated that:

*'Due to the short period between your claim and your registration deadline of 31 May 2013 and in order to enable you to fulfil your legal registration obligations, [the Agency] has allowed you to proceed with the registration without the full data set, while the data sharing dispute was processed. This permission was only temporary and did not prejudice the final outcome of the [assessment of the data sharing dispute].*

*You decided to take advantage of the contingency procedure following instructions given by [the Agency] and have submitted the registration dossier on 30 May 2013 [...]. Due to the dispute you were not able to submit all the required information (as per Article 20(2)) and you did not pass the technical completeness check (TCC). Your dossier has been recorded in REACH-IT, however, it was not processed due to the processing of the data sharing dispute claim'.*
7. On 14 August 2013, the Agency adopted a decision, pursuant to the third subparagraph of Article 20(2), informing the Data Claimant that its registration dossier was incomplete and that it was required to provide the missing information identified by the Agency by 14 August 2014. On 19 May 2014, the Agency informed the Data Claimant that, due to the appeal in Case A-017-2013 against the Agency's decision to grant permission to refer, the deadline to provide the further information requested in the Agency's decision of 14 August 2013 was suspended until after the Board of Appeal's decision in that case. The Agency informed the Data Claimant that, as a result, its registration will not be rejected if it is not completed by 14 August 2014.

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

8. On 7 August 2013, the Appellant lodged the present appeal requesting the Board of Appeal to partially annul the Contested Decision in so far as it allows the Data Claimant to temporarily proceed with its registration of vanadium without a full data set while the Agency processed the data sharing dispute between the Appellant and the Data Claimant pursuant to Article 30(3).
9. The Appellant also seeks a refund of the appeal fee and requests the Board of Appeal to confirm the suspensive effect of the appeal upon the Contested Decision, pending the decision of the Board of Appeal.
10. On 13 September 2013, since a member of the Board of Appeal was precluded from participating in the proceedings, the Chairman of the Board of Appeal, pursuant to the first subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter the

'Rules of Procedure'), designated an alternate member, Rafael Antonio López Parada, to act in the present appeal as the legally qualified member of the Board of Appeal.

11. On 25 September 2013, the European Coalition to End Animal Experiments (hereinafter 'ECEAE') applied to intervene in the proceedings before the Board of Appeal opposing the remedy sought by the Appellant. On 15 November 2013, the Board of Appeal rejected the application to intervene on the grounds that ECEAE had not established an interest in the result of the present appeal as required by Article 8(1) of the Rules of Procedure.
12. On 25 September 2013, the Data Claimant applied to intervene in the proceedings before the Board of Appeal opposing the remedy sought by the Appellant. By Decision of 15 November 2013, the Board of Appeal granted the application to intervene.
13. On 8 October 2013, the Agency submitted its Defence. On 28 November 2013, the Appellant lodged its observations on the Defence.
14. On 16 December 2013, the Intervener submitted its further observations on the procedural documents submitted in the case. On 27 January 2014, the Appellant and the Agency submitted their respective observations on the Intervener's observations.
15. On 28 February 2014, the Board of Appeal invited the Agency to respond to a number of questions. The Agency duly responded to the Board of Appeal's questions on 28 March 2014.
16. On 29 April 2014, the Appellant was invited to submit observations on the Agency's response to the Board of Appeal's questions. On 28 May 2014, the Appellant duly submitted its observations.
17. On 21 May 2014, the Agency provided the Board of Appeal with a communication it had previously sent to the Data Claimant on 19 May 2014 informing it, inter alia, that the deadline to provide the information requested pursuant to the third subparagraph of Article 20(2) had been suspended until after the decision of the Board of Appeal in Case A-017-2013.
18. On 12 June 2014, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 23 June 2014, both the Agency and the Appellant requested a hearing to be held. As a result, in accordance with Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 18 September 2014. At the hearing, the Parties and Intervener made oral presentations and also responded to questions from the Board of Appeal.

## **ARGUMENTS OF THE PARTIES AND INTERVENER**

### **Arguments of the Appellant**

19. By its first plea, the Appellant claims that there was no legal basis for the Contested Decision and that the Agency had exceeded its competence by adopting a decision granting the Data Claimant permission to proceed with its registration on a temporary basis without access to the vertebrate animal data contained in the joint submission for vanadium. In particular, the Appellant claims that this power cannot be found in Article 30(3) and that decisions adopted pursuant to that provision must be limited to a permission to refer to information submitted by another registrant. According to the Appellant, such decisions cannot create a right for a claimant to temporarily proceed with registration.

20. The Appellant argues further that the Contested Decision contains unequivocal statements that the Agency was exercising a discretionary power to grant temporary permission, such as 'in order to enable the [Data Claimant] to fulfil their legal registration obligations, [the Agency] can allow them to proceed with registration...'.
21. The Appellant also claims that for a submission of a registration dossier to be accepted it must first pass the business rules check (hereinafter the 'BRC'). In support of its argument the Appellant referred to the Agency's Data Submission Manual – Part 04 – How to Pass Business Rules Verification ('Enforce Rules' - Version 3.1, Release date April 2014), (hereinafter the 'Data Submission Manual'). According to the Appellant, in order to pass the BRC, certain information fields must be completed in REACH-IT and only if the submission passes the BRC will it proceed to the technical completeness check (hereinafter the 'TCC') foreseen in Article 20(2). The Appellant claims that in the present case the Agency instructed the Data Claimant how to circumvent the BRC so as to allow it to submit a registration dossier, which it knew to be empty, in order that the dossier could proceed to the TCC.
22. The Appellant claims further that the Agency had full knowledge that the Data Claimant would submit a materially empty dossier and that in such circumstances the Agency is under a duty to apply promptly the TCC procedure and reject the dossier rather than unduly prolong market access.
23. The Appellant states that through the Contested Decision the Agency had granted a competitive advantage to the Data Claimant as it had been allowed to temporarily register the substance and remain on the market without satisfying the information requirements of the REACH Regulation. The Appellant argues that the Agency's contingency procedure grants the Data Claimant the benefit of a registration from 1 June 2013, immediately after the applicable registration deadline, until 12 July 2013, when the decision on the data sharing dispute was taken, thus providing uninterrupted market access. The Appellant claims later in the proceedings that the Agency facilitated the Data Claimant's access to the market for vanadium to an as yet unspecified date beyond 14 August 2014, which was the date the Agency originally set in its decision of 13 August 2013 for the Data Claimant to provide the information identified as missing during the TCC.
24. The Appellant also submits that the Agency incorrectly interpreted the phase-in rules contained, in particular, in Article 23. According to the Appellant, the purpose of the phase-in rules contained in Article 23 is entirely focused on the period before a dossier submission is made. The Appellant argues that for all registrants, following the submission of a dossier, the provisions of Articles 20 and 21 apply. The Appellant highlights that, according to Article 21, '... a registrant may start or continue the manufacture or import of a substance ... if there is no indication to the contrary from the Agency in accordance with Article 20(2)...'. According to the Appellant, as a result, the failure of a data claimant to pass the first TCC requires it to stop its manufacture or import of the substance in question until the relevant dossier is complete.
25. By its second plea, the Appellant submits that it was not necessary for the Agency to adopt a decision granting a temporary registration of vanadium to the Data Claimant as the Agency could have proceeded promptly with a final decision on the data sharing dispute in full compliance with Article 30(3). The Appellant claims that the Agency's failure to do so resulted in disproportionate action.

**Arguments of the Agency**

26. The Agency claims that the appeal is inadmissible on the grounds that it challenges a mere communication which does not produce binding legal effects capable of affecting the interests of the Appellant by bringing about a distinct change in its legal position.
27. The Agency states that, according to the case-law of the Court of Justice of the European Union, a measure cannot be considered to be a decision if it is obviously unsuitable to produce binding legal effects, for example because the institution would not have been competent to take the alleged decision. According to the Agency, the REACH Regulation contains no basis to issue temporary registration decisions and none are issued by the Agency.
28. The Agency argues further that the legal situations of the Appellant and the Data Claimant were determined directly by the REACH Regulation and were not affected by the communications sent to the Appellant and the Data Claimant on 8 May 2013. The Agency claims that those communications simply summarised the phase-in scheme set out in particular in Articles 23 and 28. The Agency claims that, according to those Articles, a manufacturer or importer of a phase-in substance who has pre-registered the substance and submitted a dossier by the relevant deadline may continue manufacturing or importing that substance until the Agency issues a final decision either rejecting the registration or assigning a registration number. According to the Agency, since the right to continue manufacturing or importing a substance stems directly from the legislation it is not dependent on a decision from the Agency.
29. According to the Agency, the purpose of the Agency's contingency procedure is to ensure that the data sharing decision and the decision on technical completeness are appropriately timed. In particular, the Agency must ensure that the decision on data sharing is issued before a decision on the technical completeness of the dossier is taken. The Agency adds that, for practical reasons, a data claimant must know whether it can rely on a permission to refer to the disputed studies before being informed of the deadline to complete its registration dossier following a TCC. According to the Agency, the Agency's contingency procedure merely informs data claimants who have pending data sharing disputes which code they should enter in the relevant fields of their registration dossier to enable the Agency to link the dossier to the data sharing dispute.
30. The Agency argues further that any manufacturer or importer can submit a dossier without a full data set and therefore it granted no preferential treatment to the Data Claimant. The Agency claims that the instructions given to the Data Claimant do not grant it an advantage over other registrants as, irrespective of whether the code indicated in the Agency's contingency procedure is entered or the relevant field of the dossier is left empty, the dossier would fail the TCC.
31. The Agency claims that the statement in the Contested Decision that the permission to proceed is 'only temporary' refers to the fact that a pre-registrant who has submitted an incomplete dossier before the relevant registration deadline, as set out in Article 23, and relies on the phase-in scheme to continue the import or manufacture of a substance, can only do so until the Agency has issued a final decision on the completeness of the registration or until the relevant registration deadline has been reached, whichever is the latter.
32. In the present case, the Agency states that the Data Claimant's registration dossier of 30 May 2013 for vanadium was found to be incomplete following the TCC. Further to the TCC, and pursuant to Article 20(2), the Data Claimant was given a second deadline to complete the dossier. The Agency adds that if the Data Claimant does not

provide that information by the deadline set then the registration will be rejected pursuant to Article 20(2). The Agency points out that the Data Claimant has not yet been provided with a registration number as it has not yet submitted a complete dossier. The Agency adds that if the Data Claimant provides the missing information it will receive a registration number dated from 30 May 2013, that is to say the date of the submission of the registration dossier.

33. The Agency claims that, for transparency reasons, it had informed the Appellant in the Contested Decision of the information it had provided to the Data Claimant as it considered it important for the Appellant to be aware that the Data Claimant was entitled to submit a registration dossier and that such a submission would not have any bearing on the pending data sharing dispute. The Agency adds that it was not necessary to provide the Appellant with all the other information contained in the communication to the Data Claimant of 8 May 2013 regarding for example the code to enter in the registration dossier as it was not relevant for the Appellant.

### **Arguments of the Intervener**

34. The Intervener, also the Data Claimant in the present proceedings, supports the Agency. In particular, the Intervener argues that the Contested Decision simply explained the legal situation under the REACH Regulation and did not create any rights, or alter the legal position of either the Appellant or the Data Claimant. The Intervener also argues that the Agency's contingency procedure was necessary to ensure the full practical effect of both the phase-in and data sharing provisions of the REACH Regulation. According to the Intervener, if the Agency were required to decide whether or not to grant a registration number before it had resolved a related data sharing dispute, the registration dossier in question would necessarily be rejected as incomplete. Such a solution would devoid the phase-in scheme of any useful effects.
35. The Intervener argues that the Agency did not grant it a competitive advantage by allowing it to continue manufacturing or importing vanadium without satisfying the requirements of the REACH Regulation as a data claimant's right to remain on the market until the Agency rejects its registration clearly stems from the REACH Regulation itself.

### **REASONS**

#### **The Appellant's first plea regarding the Agency's lack of competence to allow, on a temporary basis, the Data Claimant's registration of vanadium without the full data set**

36. By its first plea, the Appellant claims in essence that there was no legal basis for the Contested Decision and that the Agency therefore exceeded its competence by adopting a decision granting the Data Claimant permission to proceed with its registration on a temporary basis without having access to data on vertebrate animal testing contained in the joint submission for vanadium.
37. The Agency claims, however, that the appeal is inadmissible on the grounds that it challenges a mere communication which does not produce binding legal effects capable of affecting the Appellant's interests by bringing about a distinct change in its legal position.
38. The Board of Appeal observes that the Appellant included as Annex 1 to its Notice of Appeal a communication from the Agency of 8 May 2013 addressed to it with the

reference DSH-30-3-0018-2013. The Appellant specified that this communication was being challenged in the present proceedings. More specifically, the Appellant indicated that it was challenging the following part of that letter:

*'Due to the short period between the complaint and the registration deadline of 31 May 2013, [the data sharing dispute] may not be concluded by that date. Therefore, in order to enable the [Data Claimant] to fulfil their legal registration obligations, [the Agency] can allow them to proceed with the registration without the full data set, while the data sharing dispute is being processed. However, you must note that this permission is only temporary and does not prejudge the final outcome of the contradictory assessment.'*

39. The Board of Appeal observes that the remainder of the letter mainly informed the Appellant about the lodging of the data sharing dispute and requested the Appellant to submit information to the Agency so that it could perform its assessment of whether every effort had been made to share the data which was the subject of the data sharing dispute. The letter also informed the Appellant that the Agency predicted that a decision on the data sharing dispute would be adopted by 22 July 2013.
40. During the present proceedings it became clear that the Contested Decision had not been sent to the Data Claimant. The Data Claimant had received a separate communication from the Agency on the same date and with the same reference number but containing different, as well as additional, information. In particular, the communication sent by the Agency to the Data Claimant contained more detailed information on the Agency's contingency procedure and the potential consequences stemming from it. The Board of Appeal observes that the communication sent to the Data Claimant contained two annexes which were not included in the letter sent to the Appellant (see paragraph 5 above). The communication addressed to the Data Claimant was not copied to the Appellant; it did, however, contain certain similar information to that contained in the part of the letter disputed by the Appellant (see paragraphs 3 and 38 above).
41. During the proceedings, the Appellant informed the Board of Appeal that the communication sent to the Data Claimant on 8 May 2013 should not be considered to be the Contested Decision and, as a result, any arguments based on that document should not be taken into consideration.
42. The Board of Appeal will therefore examine whether the letter addressed to the Appellant on 8 May 2013 can be considered to be a decision of the Agency. In this respect, the Board of Appeal considers that the contested part of the letter addressed to the Appellant (see paragraphs 3 and 38 above) shows that it is reporting the procedure applicable to the Data Claimant. For example, the wording '... to enable the claimant to fulfil their legal obligations, [the Agency] can allow them to proceed with the registration ...', coupled with the fact that the Data Claimant was not included as an addressee of the communication sent to the Appellant makes it clear that the Contested Decision was reporting a procedure applicable to another party, in this case the Data Claimant, and potentially a separate communication addressed to the Data Claimant. The Board of Appeal finds therefore that any purported decision could only have been contained in the communication addressed to the Data Claimant.
43. Since, however, the Appellant is in effect contesting the Agency's alleged decision which it considers allows the Data Claimant to proceed to the registration of vanadium without a full data set, in the interests of clarity and completeness, the Board of Appeal will examine whether the Agency in fact took any decision to this effect, irrespective of in which document that purported decision may be set out.

44. In addressing this issue the Board of Appeal will examine whether the Agency in practice, and irrespective of in which communication the purported decision was included, granted the Data Claimant the right to submit a registration dossier for vanadium and to proceed to the TCC, even though it did not at the time of submission possess all the information required by the REACH Regulation.
45. The Board of Appeal observes that the Data Claimant is a registrant of vanadium as a phase-in substance within the meaning of point 20 of Article 3. As the Data Claimant is required to register the substance at the 100 and 1000 tonnes per annum level, the Data Claimant falls within the provisions of Article 23(2). Consequently, the Data Claimant was required to submit a registration dossier before 1 June 2013. The Board of Appeal also observes that if the pre-registrant of a phase-in substance does not submit a registration dossier for the substance by the applicable registration deadline it should not import or manufacture the substance after that date; any continuation of import or manufacture of the substance may be considered to be a breach of Articles 5 and 6 of the REACH Regulation and the importer or manufacturer may be subject to enforcement action by the relevant Member State.
46. In the present case, it is clear that the Data Claimant complied with Article 23(2) in so far as it submitted a registration dossier for vanadium on 30 May 2013, in other words before the appropriate registration deadline. Furthermore, the Board of Appeal observes that the obligation for the Data Claimant to submit its registration dossier is not subject to any prior authorisation from the Agency regardless of whether a data sharing dispute is pending. The obligation to submit a registration dossier stems directly from the REACH Regulation, and in particular the provisions referred to in the previous paragraph. The Board of Appeal finds therefore that the Data Claimant's right to submit a registration dossier for vanadium was not affected by the Agency's communications of 8 May 2013.
47. Having established that the Agency did not grant the Data Claimant the right to submit a registration dossier, the Board of Appeal will next examine the Appellant's claim that, through the Agency's contingency procedure, the Agency granted preferential treatment to the Data Claimant by instructing it how to pass the BRC, despite the fact that its registration dossier was essentially empty, in order to allow it to proceed to the TCC.
48. Following the Appellant's arguments related to the BRC, the Board of Appeal put several questions to the Agency on this issue at the hearing. During the hearing the Appellant claimed that the Agency's responses regarding the BRC constitute new evidence. The Board of Appeal observes however that the claims related to the BRC were raised for the first time by the Appellant in its final submission of 28 May 2014 prior to the closure of the written procedure and that the Agency was not given the opportunity prior to the hearing to respond to those arguments. In view of this fact, the Board of Appeal considers that the Agency's delay in offering the evidence related to the BRC is justified pursuant to Article 12(1) of the Rules of Procedure. Consequently, the Board of Appeal will take into consideration the arguments raised by the Agency at the hearing in this respect.
49. During the proceedings the Appellant referred to the Data Submission Manual. The Board of Appeal observes that the purpose of the BRC is summarised in Section 2.1.1 of that document:

*'All dossiers submitted to the Agency undergo administrative checks, called "business rules". The business rules are a set of pre-requisites that must be fulfilled before [the*

*Agency] can establish that the dossier can be handled properly and that the required regulatory processes can be successfully carried out. The business rules are checked using the REACH-IT software, and exist for two reasons:*

- Format: In order to be processed correctly, REACH-IT must establish whether the dossier is in the correct IUCLID 5 format. For example, a PPORD notification must not be in the format of a registration dossier.*
- Administrative: Before accepting a dossier for processing, [the Agency] must establish that it can be properly handled. This requires that certain administrative information has to be checked to ensure that it is consistent with the submission type. For example, if the dossier is an update following a regulatory request, but the reference number provided for the previous submission is incorrect, it would be impossible to establish a link with the previous dossier. Under other circumstances, it might be unclear how the dossier should be invoiced.*

*A dossier can be accepted for processing by [the Agency] only if all of the relevant business rules are satisfied. After that, the submission can proceed to the next steps (e.g. technical completeness check (TCC) and invoicing). If the dossier submission fails at the business rule level, the dossier cannot be accepted for processing, and a new submission is required before any regulatory processes can be initiated.'*

50. The Board of Appeal finds however that the Appellant did not identify any part of the Data Submission Manual, or provide any other evidence, which would demonstrate that the information subject to the data sharing dispute is verified at the BRC stage and that the absence of that information could lead to the registration being rejected at the BRC stage. The Appellant does refer to the fact that the Data Submission Manual contains, in a number of places, the following phrase: 'Have there been any "Data Sharing issues"? This information is not part of the Business Rules check'. The Board of Appeal finds however that this does not support the Appellant's claim that the Agency assisted the Data Claimant to circumvent the BRC. On the contrary, the Board of Appeal considers that this phrase demonstrates that the existence of a data sharing dispute has, in itself, no impact on whether or not a registration dossier passes the BRC.
51. The Board of Appeal considers that, having regard to the purpose of the BRC set out in paragraph 49 above, and as confirmed by the Agency at the hearing, the absence or otherwise from a dossier of the information subject to the data sharing dispute is not verified during a BRC. The Board of Appeal finds that only at the TCC, performed pursuant to Article 20(2), does the Agency verify whether the information that is subject to a data sharing dispute is provided. As a consequence, in this particular case, whatever the Data Claimant had included in the fields concerning the information subject to the data sharing dispute, even if they had been left empty, the registration dossier would not have failed the BRC on this basis.
52. The Board of Appeal therefore concludes that the instructions contained in the Agency's contingency procedure did not assist the Data Claimant to circumvent the BRC.
53. In light of the above, the Board of Appeal finds that no decision was taken by the Agency regarding the Data Claimant's right to submit a registration dossier and to proceed to the TCC despite the absence from that dossier of the information which is the subject of the data sharing dispute in either of the communications dated 8 May 2013.

54. The Board of Appeal does however consider that the language used by the Agency in the Contested Decision may have contributed to the Appellant's impression that the Agency had taken a decision and granted specific rights to the Data Claimant. In particular, the use of wording such as '[the Agency] can allow them to proceed' and 'this permission is only temporary' could give the impression that the Agency had assessed the Data Claimant's situation and decided to grant it certain rights. The Board of Appeal observes that similar language was also included in the letter of 8 May 2013 to the Data Claimant which included phrases such as the Agency '... is allowing you to proceed with registration'. However, as stated above, the communication addressed to the Data Claimant also contained considerably more information regarding the Agency's contingency procedure which acted to clarify that no decision allowing the Data Claimant to proceed with its registration was being taken by the Agency, or was even required.
55. The lack of clarity in the Agency's communications may have also been exacerbated by the Agency's Guidance on Data Sharing (Version 2.0, April 2012, page 72) which states that 'the potential registrant must obtain a decision from [the Agency] granting the permission to refer to the information BEFORE submitting their registration' when, as demonstrated in the present case, this is not actually the case.
56. The Board of Appeal also considers that it is poor administrative practice to attribute the same reference number to two separate letters with the same date, on the same issue, with different content, to two parties.
57. Nonetheless, whilst the Board of Appeal considers that some of the communications in the present case may have contributed to the Appellant's belief that the Agency had granted certain rights to the Data Claimant, an examination of the facts and the applicable legislation demonstrates clearly that this was not the case. In particular, it is clear that the submission of the Data Claimant's registration dossier and the treatment thereof by the Agency were in accordance with the provisions of the REACH Regulation as well as the Agency's own rules on the BRC. The potentially misleading nature of the Agency's communications in the present case does not therefore alter the Board of Appeal's finding that the Agency did not take a decision in the present case permitting the Data Claimant to proceed with registration on a temporary basis or instruct the Data Claimant how to circumvent the BRC.
58. During the proceedings, the Appellant also claimed that the phase-in system and the right to continued market access, which is derived from that scheme, applies only up to the point of submission of the registration dossier and after that time the registration falls within the provisions of Articles 20 and 21 which apply to all registrations. The Appellant claims that, as a result, in this particular case, the Data Claimant should have ceased manufacturing from the date of the failure of the TCC until the time the Agency decides that its registration dossier is complete and grants the Data Claimant a registration number pursuant to Article 20(3).
59. The Board of Appeal observes that, following the TCC, pursuant to the first, second and third subparagraphs of Article 20(2), the Data Claimant's registration dossier was found to be incomplete. On 14 August 2013, the Agency consequently adopted a decision, pursuant to the third subparagraph of Article 20(2), requesting the Appellant to provide additional information by 14 August 2014. This course of action is consistent with the second and third subparagraphs of Article 20(2) which, in the circumstances of the present case, requires the Agency to perform a completeness check of the dossier within three months of the applicable registration deadline and request additional information if the dossier is found to be incomplete.

60. The Board of Appeal also observes that it is within the Agency's discretion to carry out the TCC at any point within the three months granted to it under the second subparagraph of Article 20(2), regardless of whether there is a pending data sharing dispute. The Board of Appeal also observes that the Agency had not, at the time of the oral hearing, assigned the Data Claimant a registration number as the registration dossier is still incomplete. In this respect, the Agency has acted in accordance with the third subparagraph of Article 20(2) and Article 20(3).
61. For the sake of clarity, the Board of Appeal observes that, in the present proceedings, the Appellant is not contesting the Agency's decision of 14 August 2013, adopted under the third subparagraph of Article 20(2), which finds that the registration dossier is incomplete. In this respect the specific information requested in that Agency decision to make the dossier complete and the amount of time permitted to provide that information are not contested by the Appellant.
62. The Appellant does claim, however, that, according to Article 21, the Data Claimant should have ceased manufacture of vanadium from the date of the failure of the TCC until the time the Agency subsequently takes a decision that its registration dossier is complete and grants the Data Claimant a registration number. The Board of Appeal observes, however, that if a manufacturer or importer fails to correctly register a substance in accordance the REACH Regulation, Article 126 foresees that the Member States shall have in place provisions on penalties applicable to such infringements. It is therefore the responsibility of the Member State enforcement authorities concerned to take action if they consider that a manufacturer or importer has failed to register a substance in accordance with the REACH Regulation. This task is performed in the context of enforcing Article 5, in other words in ensuring that substances on their own, in mixtures or in articles, subject to Articles 6, 7, 21 and 23, are not manufactured in the European Union or placed on the market unless they have been registered.
63. The responsibility to verify whether companies have complied with the provisions of the REACH Regulation regarding the registration of the substances they manufacture or import therefore falls within the competence of the Member States. As a result, the Board of Appeal considers that neither the Agency nor the Board of Appeal is competent to decide whether a registrant, which has submitted a registration dossier for a phase-in substance by the deadline set in Article 23, has failed the TCC under the third subparagraph of Article 20(2), and has not yet received a registration number pursuant to Article 20(3), is permitted to continue manufacturing or importing a particular substance until a registration number is assigned by the Agency. The Board of Appeal also considers that it is clear from the facts of the case that the Agency did not take any decision to that effect in either of the communications of 8 May 2013 addressed to the Appellant and the Data Claimant.
64. In view of the above, the Board of Appeal considers that the right to proceed with registration emanates directly from the REACH Regulation; this right was not altered in any way by the Agency's communications of 8 May 2013 sent to the Appellant and the Data Claimant. As a result, no decision was taken by the Agency regarding the Data Claimant's right to submit a registration dossier. In addition, the Agency did not provide the Data Claimant with guidance aimed at allowing it to circumvent the BRC so that it could proceed to the TCC. The Board of Appeal also considers that the communications sent by the Agency to the Appellant and the Data Claimant on 8 May 2013 did not contain any wording that would unduly influence the outcome of the data sharing dispute or grant any permission to refer to the data subject to that dispute, even on a temporary basis. The Appellant's plea that the Agency acted illegally in granting a temporary right to proceed with registration without a full data set must therefore be dismissed as unfounded. In the light of the Board of Appeal's

finding that no decision of the sort alleged by the Appellant was taken by the Agency in either of the communications of 8 May 2013, the appeal must be dismissed as inadmissible.

65. In view of the fact that the Board of Appeal has decided that no decision was taken in the present case and that the appeal is inadmissible, it is not necessary to examine the Appellant's second plea.
66. In accordance with Article 10(3) 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), as the Board of Appeal has decided that the appeal is inadmissible, the appeal fee shall not be refunded.

## **ORDER**

On those grounds,

THE BOARD OF APPEAL

hereby:

**Dismisses the appeal.**

Mercedes ORTUÑO  
Chairman of the Board of Appeal

Sari HAUKKA  
Registrar of the Board of Appeal