

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

23 August 2016

(Biocidal products - Data sharing dispute - Permission to refer - Every effort)

Case number	A-005-2015
Language of the case	English
Appellant	Thor GmbH, Germany
Representative	Koen Van Maldegem and Peter Sellar Field Fisher Waterhouse LLP
Contested Decision	Decision [CONFIDENTIAL] of 26 January 2016 adopted by the European Chemicals Agency pursuant to Article 63(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1; hereinafter the 'BPR')

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member) and Sari Haukka (Legally Qualified Member and Rapporteur)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 3 March 2015, the Appellant lodged the present appeal at the Registry of the Board of Appeal against the Contested Decision. By the Contested Decision, the European Chemicals Agency (hereinafter the 'Agency') granted permission to a company (hereinafter the 'prospective applicant') to refer to studies owned by the Appellant concerning the substance reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (hereinafter the 'Substance' or 'CIT/MIT'). The prospective applicant had notified the Agency on 23 October 2014, pursuant to Article 63(3) of the BPR (all references to Articles hereinafter concern the BPR unless stated otherwise), of a failure to reach an agreement with respect to the sharing of the data contained in these studies with the Appellant. The prospective applicant was seeking access to studies owned by the Appellant in order to apply for inclusion in the list of suppliers of biocidal products and substances which have not yet been approved and that the Agency publishes pursuant to Article 95 (hereinafter the 'Article 95 list').

Background to the dispute

2. Since December 2012, the Appellant and the prospective applicant had been in contact concerning the possibility of concluding a data sharing agreement related to the Substance. The prospective applicant was anticipating its upcoming obligation to apply to be included in the Article 95 list. On 10 December 2012, the Appellant informed the prospective applicant that it could issue, in exchange for payment, a letter of access for two studies on the Substance. The two studies concerned the potential genotoxic effects of the Substance (hereinafter the 'two genotoxicity studies').
3. On 16 September 2013, the Appellant informed the prospective applicant that a data sharing agreement could be concluded on the condition that an independent consultant carries out an assessment of technical equivalence (hereinafter the 'technical equivalence assessment') between the active substance supplied by the prospective applicant (hereinafter the 'prospective applicant's active substance') and the Substance supplied by the Appellant.
4. By letter dated 18 September 2013, the Agency informed the Appellant that it had received a written request from the prospective applicant in accordance with Article 62(2) to determine whether tests or studies on the Substance had already been submitted to the Agency. The Agency also informed the Appellant that it had provided the Appellant's contact details to the prospective applicant and outlined the data sharing obligations set out in Articles 62 and 63.
5. On 23 September 2013, the Appellant and the prospective applicant agreed during a teleconference to ask the Member State which acted as Rapporteur for the evaluation of the Substance (hereinafter the 'Rapporteur Member State') in accordance with Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1; hereinafter the 'BPD') whether it would agree to conduct a technical equivalence assessment. The prospective applicant also agreed to a consultant performing a technical equivalence assessment, should the Rapporteur Member State refuse to do so.
6. On 1 October 2013, the prospective applicant indicated that, in addition to the two genotoxicity studies, it also sought access to a third study on absorption, metabolism

and excretion following oral administration of the Substance to rats (hereinafter the 'third study').

7. After an exchange of emails on 23 and 30 October 2013, the prospective applicant and the Appellant agreed that the Appellant would give access to the reports on the two genotoxicity studies and the third study (hereinafter the 'three studies') to a toxicologist proposed by the prospective applicant (hereinafter the 'toxicologist') for a quality and usability check.
8. On 14 and 18 November 2013 respectively, the Appellant and the prospective applicant signed an *'every effort and secrecy agreement under the Biocidal Products Regulation for CIT/MIT'* (hereinafter the 'every effort agreement'). The every effort agreement established as its scope and purpose *'the mutual understanding of the Parties to undertake Every Effort in accordance with Articles 62 and 63 of the [BPR] in order to share data, against fair compensation, and, if successful, to conclude: either a "Data Sharing Agreement under Article 95 of the [BPR]" covering at least but not limited to "toxicological and ecotoxicological studies, including tests not involving vertebrate animals"; or a "Data Sharing Agreement for authorization of biocidal products containing CIT/MIT" covering at least but not limited to "vertebrate animal studies"'*.
9. On 18 November 2013, the prospective applicant informed the Appellant that, as the Rapporteur Member State had declined to perform a technical equivalence assessment, it would request the Agency to perform a technical equivalence assessment of the prospective applicant's active substance and the Substance supplied by the Appellant.
10. On 6 December 2013, the prospective applicant informed the Appellant that the Agency had replied to the inquiry concerning the possibility of the Agency performing the technical equivalence assessment and that the Agency had stated that *'[...] this practice is not legally compliant. Since a technical equivalence cannot be done for non-approved substances, data owners do not have the right to demand any form of similarity check as a pre-requisite for getting a letter of access'*. In the same message, the prospective applicant indicated that *'although it may not be legally compliant, [the prospective applicant agrees] to the establishment of technical equivalence/similarity in principle'* and suggested to the Appellant a list of three consultants for the task, requesting the Appellant to pay a share of the costs of the technical equivalence assessment.
11. On 11 December 2013, the Appellant responded and asked whether the prospective applicant would accept a counterproposal concerning the consultants suggested by the prospective applicant as those consultants *'were not very well known'* to it. On the same day, the prospective applicant replied with some background details about the consultants it had proposed and asked the Appellant to take *'a closer look'* at the suggested list. On 17 December 2013, the Appellant provided the names of two other consultants, asking the prospective applicant if it *'would accept other names'*.
12. On 31 January 2014, the prospective applicant sent an email to the Appellant in which it agreed to have the technical equivalence assessment performed by one of the consultants identified by the Appellant (hereinafter the 'technical equivalence consultant'). In this message, the prospective applicant also explained that it owned a study on chromosome aberration in mice on the prospective applicant's active substance, following the OECD test guideline 475, which showed positive results (hereinafter 'the positive genotoxicity study'). The prospective applicant also told the Appellant in this message that *'[the prospective applicant] is looking for studies that*

can be used in a weight of evidence approach to invalidate [the positive genotoxicity study]'.

13. On 21 May and 10 June 2014 respectively, the prospective applicant and the Appellant signed an agreement relating to *'the procedure and handling fee concerning a possible Data Sharing agreement in accordance to [Article] 95 of the [BPR]'* (hereinafter the 'procedure and handling fee agreement'). The procedure and handling fee agreement included an option for the *'review of certain studies by an independent consultant exclusively for the quality verification of the studies required by the prospective applicant'* with the consultant being *'engaged and paid by the prospective applicant'*.
14. Between 16 and 24 June 2014, the prospective applicant and the Appellant exchanged several emails relating to the procedure and handling fee agreement and confirmed that the agreement was sent, received and signed by both of them. The prospective applicant also indicated that it had requested the toxicologist to contact the Appellant in order to set a meeting to discuss the review of the three studies.
15. On 30 June 2014, the Appellant informed the prospective applicant by email that, in preparation for the technical equivalence assessment and *'in order to find an explanation for the deviating result of [the positive genotoxicity study]'*, the Appellant had analysed and compared samples of the prospective applicant's active substance obtained from the market with batches of the Substance manufactured by the Appellant. The Appellant also informed the prospective applicant that the samples of the prospective applicant's active substance contained impurities that may explain the results of the positive genotoxicity study. The Appellant concluded that the samples of the prospective applicant's active substance did not fulfil the *'pre-requisite for chemical similarity [and] technical equivalence'* with the Appellant's substance. The prospective applicant answered on the same day that it disagreed with the initiative of the Appellant to perform analyses on samples of the prospective applicant's active substance and stated that it was expecting the Appellant to agree on a meeting with the toxicologist for the review of the three studies. The prospective applicant further indicated that any further delay by the Appellant in contacting the toxicologist and sending samples for the technical equivalence assessment would be interpreted as a failure of the data sharing negotiations and that the prospective applicant would in consequence turn to the Agency to resolve the dispute.
16. On 3 July 2014, the Appellant answered that it had examined samples of the prospective applicant's active substance as placed on the market and had doubts as to the chemical similarity of the Substance supplied by the Appellant and the prospective applicant's active substance. The Appellant further indicated that, in these circumstances, it could not send any data to the technical equivalence consultant and requested the prospective applicant *'to make sure that only material is placed on the market [...] which corresponds to the quality demands that are actually fixed by the [Rapporteur Member State]'*.
17. On 8 July 2014, the prospective applicant replied to the Appellant that it interpreted the examination of the samples of the prospective applicant's active substance by the Appellant as a breach of contract as this was contrary to the every effort agreement. The prospective applicant reiterated that it expected the Appellant to send a five batch analysis of its active substance to the technical equivalence consultant by 24 July 2014.
18. On 22 July 2014, the Appellant sent a letter to the Agency in which it explained that it had analysed samples of the prospective applicant's active substance and that it had identified *'an important difference with regards to the impurity profile between [its] and [the prospective appellant's] material'*. It added that it was worried that if the

prospective applicant's products containing the active substance were placed on the market it would *'pollute the market'* due to a high presence of hazardous impurities, namely nitrosamines. The Appellant further highlighted to the Agency its concern that the prospective applicant sought access to the Appellant's data in order *'to argue [the findings of the positive genotoxicity study] away'*. The Appellant concluded the letter by requesting the Agency to conduct a chemical similarity check including an analysis of the data on the nitrosamines contained in the prospective applicant's active substance.

19. On 23 July 2014, the Appellant informed the prospective applicant of its communication to the Agency. It also informed the prospective applicant that a date had been set for the toxicologist to examine the reports on the three studies. The Appellant also informed the prospective applicant that *'[n]umerous times we have informed you that we have impurities detected on batches which we regularly bought on the market. These impurities aren't contained in our material and they may be the reason for the results in [the positive genotoxicity study]. Thus, before we grant the comparison of the five batch analyses through [the technical equivalence consultant], it is important to clarify this issue first'*. The Appellant added that *'[t]hus the deadline set by yourself of 24th July is not relevant for us. We expect a statement from [the Agency] within the next days and will contact you again'*. On 1 August 2014, the Agency informed the Appellant that a *'[t]echnical equivalence or chemical similarity check are not legally required (nor relevant) for data sharing, and potential discrepancies between the reference source and an alternative source cannot be a justification to refuse sharing data'*. The Agency added that *'the BPR requires the technical equivalence at the stage of product authorisation after the active substance approval decision has been adopted'*.
20. On 11 August 2014, the Appellant informed the prospective applicant that the toxicologist had reviewed the reports on the three studies owned by the Appellant.
21. On 30 September 2014, the Appellant addressed a letter to the European Commission voicing concerns that *'[the Agency's] conclusion such that a chemical similarity check is neither required nor relevant in the context of data sharing, which effectively amounts to allowing the placing on the market of non-compliant specifications that meet the exclusion criteria under Article 5 [...] pending the approval decision, contravenes both the spirit of the BPR and the precautionary principle'*. In the same letter, the Appellant *'[strongly urged] the European Commission to state its views on the matter, in particular the correct interpretation of data sharing provisions under the BPR and what appropriate, preventive actions should be taken by [the Agency] and/or the Commission'*.
22. On 2 October 2014, the European Commission responded in an email to the Appellant that *'we agree with [the Agency's] interpretation set out in the letter of 1 August 2014 in which it stated that technical equivalence or chemical similarity are not legal requirements for data sharing under Article 62 and 63'* and that *'we take this opportunity to further clarify that technical equivalence or chemical similarity are not conditions for an application to be included on the Article 95 list'*.
23. On 23 October 2014, the prospective applicant informed the Agency of the failure to reach an agreement on data sharing with the Appellant. The prospective applicant had sought access to data for an application to be included in the Article 95 list as a supplier of an active substance that has not yet been approved. With its claim, the prospective applicant submitted documentary evidence of the different steps in the negotiations with the Appellant. Consequently, on 6 November 2014, the Agency

- requested the Appellant to provide documentary evidence of the different steps in the negotiations with the prospective applicant.
24. On 17 November 2014, the Appellant sent a message to the prospective applicant stating that the Appellant was willing to continue negotiations on data sharing *'where we have left our last exchange, forwarding our [five] batch analysis data [on the Substance] to the [the technical equivalence consultant], to have them conducting on that basis a chemical similarity check'*.
 25. On 20 November 2014, the Appellant provided to the Agency a summary of its negotiations with the prospective applicant and attached the related evidence. The Appellant also stressed that in its view the negotiations were ongoing.
 26. On 21 November 2014, the prospective applicant wrote to the Appellant that *'[it was] very pleased to see that the data sharing negotiations can continue'*. It added that *'[it was] glad to learn that [the Appellant] was now willing to send [its five batch analysis]'*.
 27. On 1 December 2014, the Appellant answered that it never considered the negotiation process as having failed.
 28. On 8 December 2014, the prospective applicant, in a message to the Appellant, explained that it considered that the Appellant had *'violated the every effort agreement in major parts'* by not sending the data to the technical equivalence consultant. The prospective applicant added that *'[its] counterproposal is to proceed with the data sharing the way it is foreseen by the BPR: Technical equivalence is not a precondition for data sharing at the active substance level'*.
 29. On 15 December 2014, the Appellant replied that *'[it still felt that] conducting a similarity check at this stage would be the right thing to do and particularly beneficial to [the prospective applicant] as [the prospective applicant] would have insurance the data [it] purchase[s] are based on a material chemical [sic] similar to [the prospective applicant's active substance]'*. The Appellant also indicated that it was *'currently preparing the data exchange agreement which will include all relevant details'*. The Appellant also asked if the prospective applicant was *'still interested in purchasing worldwide use rights for regulatory purposes for the two genotoxicity studies or is [the prospective applicant] only interested in a [Letter of Access] for BPR purpose only'*.
 30. On 18 December 2014, the prospective applicant replied that it was *'awaiting [the Appellant's] draft data exchange agreement for worldwide use'*.
 31. On 13 January 2015, the Appellant sent the prospective applicant a *'Data Sharing Agreement Draft for Worldwide use for CIT/MIT'* for the prospective applicant's comments.
 32. On 14 January 2015, the prospective applicant answered that it was *'for the time being, no longer interested in data sharing with [the Appellant]'*.
 33. On 19 December 2014 and 13 January 2015, in order to update the documentation relating to the data sharing dispute, the Appellant sent to the Agency a transcript of several emails exchanged between the Appellant and the prospective applicant. The Agency informed the Appellant on 13 January 2015 that *'for the purposes of [the data sharing dispute], [the Agency] will take into account only negotiations up to the date of the submission of the dispute claim'*. On 15 January 2015, the Appellant answered that *'[it] continued the exchange with [the prospective applicant] in good faith'* after the data sharing dispute was submitted by the prospective applicant. It added that *'[o]bviously, [the prospective applicant] is no longer interested in gaining access to [the Appellant's] data'*. The Appellant attached to this communication to the Agency a

message showing, in the Appellant's view, that the prospective applicant was no longer interested in gaining access to the Appellant's data.

34. Later on the same day, the Agency sent a draft decision to the prospective applicant indicating that it *'intends to grant [the prospective applicant] permission to refer to the studies requested from [the Appellant], provided that [the prospective applicant] provide proof to ECHA that [it has] paid the [Appellant] a share of the cost incurred pursuant to Article 63(3).'*
35. On 23 January 2015, according to the Contested Decision, the prospective applicant made an explicit request to the Agency to limit the scope of the Agency's decision to the two genotoxicity studies.
36. The prospective applicant also informed the Appellant on the same date that *'you should have received a copy of the draft decision of [the data sharing dispute]. This is to inform that we have made a payment to you. We have adapted the calculation to the current situation: Only two studies via [the Agency's] decision. This means that we do not have some of the papers we would usually have and we have consequently taken these deficits out of the calculation. As [the Agency] stated you have been breaching all agreements. Therefore we are no longer obliged to make any payment discussed under these agreements. Consequently we have deducted the [sum] we paid to you from the payment for the data. The remaining sum has been transferred to your account'.*
37. On 26 January 2015, the Agency notified the Contested Decision to the prospective applicant and addressed a copy to the Appellant. By the Contested Decision, the Agency granted the prospective applicant permission to refer to the two genotoxicity studies. In the Contested Decision, the Agency found that the Appellant had not made every effort to reach an agreement as it had made technical equivalence a unilateral pre-condition for the sharing of data on the Substance. The Agency stated further that *'a data owner cannot bring reasons of public interest to refuse data sharing, such as claiming that he has to ensure that quality standards are respected or risk management measures apply. Those tasks are undertaken by the relevant authorities of the Member States in the public interest, in accordance with national rules as provided by Article 89(2) [of the] BPR and subject to the appropriate procedural rights and guarantees'.* The Agency also found that the Appellant, by carrying out an assessment of the chemical similarity of the prospective applicant's active substance with the Substance supplied by the Appellant, had changed its position in the negotiations after agreeing that a technical equivalence assessment should be conducted by an external consultant. The Agency considered that this change *'[showed] lack of reliability and consistency and thereby [constituted] a lack of efforts'.* The Agency considered on the other hand that the prospective applicant *'had forwarded [its] data to the [technical equivalence consultant] and kept the negotiations going by displaying flexibility and providing prompt replies'.*

Procedure before the Board of Appeal

38. On 3 March 2015, the Appellant filed the present appeal. The Appellant requests the Board of Appeal to annul the Contested Decision and order the Agency to refund the appeal fee.
39. On 4 May 2015, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.

40. Following consultation with the Parties, the appeal proceedings were stayed between 7 July and 1 September 2015 in accordance with Article 25 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').
41. On 22 September 2015, the Board of Appeal invited the Appellant to provide observations on the Defence.
42. On 1 October 2015, the Agency informed the Board of Appeal that the prospective applicant had submitted a successful application under Article 95 for its active substance and would be included in the Article 95 list. The Agency further informed the Board of Appeal that the data the prospective applicant had submitted was sufficient for the Article 95 application without the need to rely on the Agency's suspended permission to refer to the Appellant's data.
43. On 15 October 2015, the Appellant submitted observations on the Agency's letter of 1 October 2015, stating that the inclusion of the prospective applicant in the Article 95 list meant that the prospective applicant did not need access to the Appellant's data, depriving the Contested Decision of its purpose. The Appellant indicated that it nevertheless maintained the present appeal and requested that the prospective applicant withdraw its data sharing dispute and its request to share the Appellant's data. The Appellant also asked the Board of Appeal to take, *ex officio*, a summary decision in its favour as the Agency had lost its interest in continuing to defend the Contested Decision.
44. On 28 October 2015, the Registry of the Board of Appeal replied to the Appellant that the Rules of Procedure do not give the Board of Appeal the possibility to decide *ex officio* in favour of either of the Parties. It was further indicated that the Chairman of the Board of Appeal had decided that the appeal proceedings should continue in accordance with the procedure foreseen in the Rules of Procedure.
45. On 3 November 2015, the Appellant lodged its observations on the Defence.
46. On 11 November 2015, following a change in the composition of the Board of Appeal, a new Rapporteur was appointed for this case.
47. On 10 December 2015, the Board of Appeal submitted written questions to the Agency. On 18 February 2016, the Agency responded to these questions and submitted observations on the Appellant's observations on the Defence.
48. On 3 March 2016, the Parties were notified of the Board of Appeal's decision to close the written procedure. On 16 March 2016, the Appellant requested a hearing to be held. In accordance with Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 21 April 2016. At the hearing, the Parties made oral presentations and responded to questions from the Board of Appeal.

Reasons

49. In support of its appeal, the Appellant raises in essence five pleas in law which may be summarised as follows.
50. By its first plea, the Appellant contends that Article 62 should not have been applied to its negotiations with the prospective applicant as the prospective applicant's intention was, in the Appellant's view, not to '*perform test or studies*' in accordance with this Article but to build a weight of evidence justification to negate the findings of the prospective applicant's positive genotoxicity study.

51. By its second plea, the Appellant submits that the mandatory requirements for the application set out in Article 63(3) were not fulfilled as the Agency adopted the Contested Decision despite the fact that the prospective applicant had not informed the Appellant that it had lodged the data sharing dispute or provided a proof of payment within the mandatory deadline set in Article 63(3). Furthermore, the Appellant claims that the Agency should have adopted the Contested Decision within 60 days of being informed by the prospective applicant of the failure of the data sharing negotiations.
52. By its third plea, the Appellant submits that the Agency did not respect the Appellant's right to be heard as the Agency, in collecting evidence from the Appellant for the purpose of the data sharing dispute, only took into account information exchanged between the Appellant and the prospective applicant up to 23 October 2014, the date when the prospective applicant submitted its data sharing dispute to the Agency. The Appellant also submits that the Agency only took into account information which was exchanged between the Appellant and the prospective applicant and that it was impossible for the Appellant to make its views known effectively when, for instance, letters sent by the Appellant to the Agency and the European Commission were not considered in the assessment of the every effort criterion simply because they had not been copied to the prospective applicant. The Appellant adds that the Agency had not given it access to all the evidence submitted by the prospective applicant in the course of the data sharing dispute.
53. By its fourth plea, the Appellant submits that the Agency concluded incorrectly in the Contested Decision that the Appellant had failed to make every effort. The Appellant considers under this plea that the Agency committed a manifest error of assessment in finding for the prospective applicant.
54. By its fifth plea, the Appellant alleges that the Agency infringed the precautionary principle as it did not take into account the fact that a technical equivalence assessment was needed as the prospective applicant's active substance might include hazardous impurities.
55. Firstly, the Board of Appeal will examine the Appellant's fourth plea, alleging that the Agency made an error of assessment regarding the every effort condition in Article 63(3).

The fourth plea alleging that the Agency made a manifest error of assessment regarding the every effort condition in Article 63(3)

Arguments of the Parties

56. The Appellant claims that the Agency concluded incorrectly in the Contested Decision that the Appellant had failed to make every effort in the data sharing negotiations. The Appellant submits further that, contrary to the Agency's finding, it was the prospective applicant that failed to make every effort. The Appellant argues that it adopted a consistent approach in the negotiations regarding the need for a technical equivalence assessment as a pre-requisite for data sharing. Furthermore, the every effort agreement, which confirms this point of view, was signed by both the Appellant and the prospective applicant. The Appellant explains in this regard that after initially requesting an assessment of the impurities in the prospective applicant's active substance, it agreed with the prospective applicant to conduct a technical equivalence check without checking the impurities and agreed, eventually, to waive the technical equivalence assessment altogether. The Appellant explains that it sent a worldwide

- use data sharing agreement to the prospective applicant for the two genotoxicity studies. The Appellant also indicates that after it contacted the Agency and the European Commission to get their opinion on the relevance of technical equivalence to the data sharing negotiations the prospective applicant's reaction was to *'sit silent for three months'*. Furthermore, the prospective applicant made *'no attempt to progress matters directly with the Appellant between 23 July and 23 October 2014'*. The Appellant therefore considers that the prospective applicant lodged the data sharing dispute prematurely.
57. The Appellant further argues that the prospective applicant acted inconsistently and unreliably when it informed the Appellant that it was pleased to continue the negotiations even though the prospective applicant had already submitted the data sharing dispute. The Appellant claims that although the prospective applicant contractually agreed through the every effort agreement to a technical equivalence assessment it subsequently argued that this assessment should not be conducted. The Appellant adds that the prospective applicant rejected the draft data sharing agreement sent by the Appellant on 13 January 2015. The Appellant argues further that the prospective applicant, after negotiating access to the two genotoxicity studies, subsequently stated that it was no longer interested in data sharing. The Appellant also indicates that the prospective applicant unilaterally refused to pay the handling fee agreed between the Appellant and the prospective applicant on 10 June 2014.
58. The Appellant also claims that the Agency erred in concluding that the Appellant, in *'carrying out unilaterally'* an impurities check on samples of the prospective applicant's active substance, demonstrated a lack of effort in the negotiations. It also argues that this argument should not form part of the Agency's reasoning as there is nothing legally to prevent the Appellant from conducting the technical equivalence assessment.
59. According to the Appellant, the prospective applicant is the owner of an in vivo genotoxicity study on the Substance which has a positive result. With regard to the Agency's finding in the Contested Decision that the Appellant *'[insisted] on discussing technical equivalence on the basis of a test that [the Appellant] carried out unilaterally and the details of which [it] did not disclose'*, the Appellant submits that it did disclose details of the impurities assessment to the prospective applicant. In particular, the Appellant informed the prospective applicant by email of 30 June 2014 that *'[it had] noted that the [prospective applicant's] material in comparison to [the Appellant's] material contains impurities of a substance class which may be responsible for the doubtful results [of the positive genotoxicity study]'*. In response to the statement in the Contested Decision that the Appellant had changed its approach to technical equivalence during the negotiations by performing its own check of the prospective applicant's active substance, the Appellant states that it gave explanations to the prospective applicant concerning its approach to technical equivalence on two occasions, namely by emails of 30 June and 3 July 2014.
60. The Appellant adds that the Agency was incorrect in finding in the Contested Decision that the Appellant lacked credibility and reliability in the negotiations. The Appellant contests the finding that *'it is part of making "every effort" to explain the reasons for this change of mind [concerning the Appellant's approach to technical equivalence]'*. The Appellant argues that it informed the prospective applicant through a series of emails and a letter of 22 July 2014 that it would not submit any data on the Substance to the technical equivalence consultant until both parties agreed that impurities would be covered by the technical equivalence assessment because of *'the potential health risk associated with [the prospective applicant's] substance'*. The Appellant adds that

it repeated these explanations in the letter addressed to the European Commission on 30 September 2014. The Appellant states further that by carrying out a chemical similarity check it merely sought to clarify the scope of the technical equivalence assessment and gave reasons for this based on the public interest. The Appellant concludes that its conduct in the data sharing negotiations was therefore not lacking credibility and reliability.

61. The Agency is of the opinion that the prospective applicant did not lodge the data sharing dispute prematurely as the data sharing negotiations had reached a standstill. The Agency further explains that the negotiations had reached an impasse because of the Appellant's insistence on investigating the impurities in the prospective applicant's active substance. Addressing the Appellant's claim that the prospective applicant should have contacted the Appellant between 23 July and 23 October 2014, the Agency states that the prospective applicant could not have known when the Appellant's discussion with the Agency and the Commission would have reached a conclusion. Concerning the Appellant's argument that the data sharing dispute was lodged prematurely, the Agency relies on the decision of the Board of Appeal of 17 December 2014 in Case A-017-2013, *Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein*. According to the Agency, in that decision the Board of Appeal stated that the assessment of the parties' efforts should not be too 'formulaic'. The Agency points out that it was clear from the prospective applicant's email of 30 June 2014 that it would lodge a data sharing dispute claim if the Appellant did not send a sample of the Substance to the technical equivalence assessment as contractually agreed.
62. Concerning the efforts made by the parties to the data sharing dispute, the Agency argues that the Appellant breached the every effort agreement when it refused to send its sample of the Substance to the technical equivalence consultant. The Agency adds that the Appellant did not provide an explanation for departing from the agreed approach to establish technical equivalence. Furthermore, the Appellant did not explain why its analysis would be a better basis for discussions on technical equivalence than an analysis by the technical equivalence consultant, nor why it would be appropriate to assess technical equivalence between the parties first, and then request a third party to repeat the assessment. The Agency further states that it did not argue in the Contested Decision that the Appellant failed to explain why the technical equivalence assessment would be necessary. Rather, it found that the Appellant had failed to make every effort by not explaining why a technical equivalence assessment should not be performed by a third party as agreed.

Findings of the Board of Appeal

63. The Board of Appeal notes that the Appellant's arguments under this plea concern in essence the assessment by the Agency of the negotiations between the Appellant and the prospective applicant up to the submission of the data sharing dispute on 23 October 2014.
64. Where an appellant claims that the Agency has made an error of assessment, the Board of Appeal must examine whether the Agency has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached (see Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 42; see also, by analogy, Case T-71/10, *Xeda International and Pace International v Commission*, EU:T:2012:18, paragraph 71 and the case-law cited).

65. The Board of Appeal observes firstly that, when applying Article 63 in the context of a data sharing dispute, the Agency's assessment is limited to whether the parties *'[made] every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant'*. It is evident from Article 63(1), which states that *'the prospective applicant and the data owner shall make every effort to reach an agreement'*, that this assessment concerns the efforts of both parties in a data sharing dispute. Therefore, the assessment of every effort requires the examination of the efforts of both parties to a data sharing negotiation. The Agency's Guidance on Data Sharing (Version 2.0, April 2012), which applies to data sharing in the context of the BPR pursuant to footnote 1 of Article 63(4), also confirms that the Agency *'performs an assessment of whether a party has breached its obligation to make every effort on the basis of the documentation provided by both parties [...]'*. The use of the word *'both'* shows that the Agency is called upon to examine the efforts of the data owner and the party requesting the data. The Board of Appeal will therefore consider the balance of efforts between the Appellant and the prospective applicant, and whether this balance is correctly reflected in the Contested Decision.
66. The Agency stated in the Contested Decision that *'the prior assessment of [technical equivalence] by a third party was a demand by the Data Owner, and it was a concession by the Prospective Applicant to agree to such an assessment at their own expense'*. However, the Board of Appeal notes that the Appellant and the prospective applicant were in contact from December 2012 to discuss the prospective applicant's access to the Appellant's studies on the Substance. On 16 and 23 September 2013, the Appellant and the prospective applicant discussed the relevance of technical equivalence to their negotiations and the prospective applicant agreed that this assessment would be performed.
67. The Board of Appeal notes that Recital ix of the every effort agreement signed by the Appellant and the prospective applicant on 14 and 18 November 2013 respectively stipulates that *'the Parties further recognize that having the chemical similarity or technical equivalence between their respective active substances specifications, in terms of purity level and nature of impurities, established should be made part of their efforts to reach a data sharing agreement'*. The Board of Appeal notes further that Sections 7.1 to 7.3 of the every effort agreement are worded as follows:
- '7.1 No information will be disclosed to either Party pursuant to Article 3 of this Agreement, unless and until Every Effort has been made by the Prospective Applicant to establish Technical Equivalence, or Chemical similarity of its CIT/MIT with that of the Data Owner.*
- 7.2. Technical Equivalence or Chemical Similarity of the Parties respective CIT/MIT specifications shall, where possible, be assessed by the Agency, by the Rapporteur Member State for CIT/MIT, or, when this is not possible, by a technical consultant chosen by the Parties, in accordance with Article 54 of the Biocidal Products Regulation.*
- 7.3. The Prospective Applicant accepts to pay any fees for a Technical Equivalence or Chemical Similarity check and the Data Owner agrees to provide any Information needed to the Agency, the Rapporteur Member State, or, where applicable, consultant, for the purpose of undertaking this task'.*
68. The Board of Appeal also notes that after a telephone conference held between the Appellant and the prospective applicant on 23 September 2013, the Appellant and the prospective applicant agreed to ask the Rapporteur Member State responsible for the evaluation of the Substance under the BPD whether it would conduct a technical

equivalence assessment. Following the refusal of the Rapporteur Member State to perform the technical equivalence assessment, the prospective applicant informed the Appellant on 18 November 2013 that it was 'currently asking' the Agency whether it would conduct a technical equivalence assessment.

69. On 6 December 2013, the prospective applicant informed the Appellant that its request to the Agency regarding the need for a technical equivalence assessment had received the following reply: '*[w]e, from [the Agency's] side, can confirm that this practice is not legally compliant. Since a technical equivalence cannot be done for non-approved substances, data owners do not have the right to demand any form of similarity check as a pre-requisite for getting a letter of access*'. The prospective applicant added in the same email that '*[d]espite of this answer and although it may not be legally compliant we agree to the establishment of technical equivalence/similarity in principle, but, facing this answer from [the Agency], we would like to ask you for a participation in the costs for the consultant which is now needed*'.
70. In view of these events, the Board of Appeal observes that the Appellant and the prospective applicant not only discussed technical equivalence early in their negotiations but also agreed contractually to the need for a technical equivalence assessment. The prospective applicant also confirmed that it agreed to make the data sharing agreement conditional upon the performance of a technical equivalence assessment even after the Agency had stated that such an assessment was not legally required.
71. The Board of Appeal therefore finds that when stating that '*the prior assessment of [technical equivalence] by a third party was a demand by the Data Owner, and it was a concession by the Prospective Applicant to agree to such an assessment at their own expense*', the Agency did not assess the circumstances of the present case correctly. Specifically, the Agency did not take into account the various instances in which the Appellant and the prospective applicant agreed between themselves to the performance of the technical equivalence assessment.
72. The Agency also failed to take into account that when the BPR became applicable on 1 September 2013 it was not yet clear to the Appellant and the prospective applicant whether assessing technical equivalence was a pre-requisite for an application to be included in the Article 95 list. This is confirmed by the various exchanges the Appellant and the prospective applicant had with the Agency and the European Commission.
73. Furthermore, the Agency erred in its assessment of the circumstances of the present case when stating in the Contested Decision that '*a data owner cannot unilaterally make [technical equivalence] a pre-requisite for data sharing*'. In fact, as demonstrated by the events described in the previous paragraphs, the requirement to conduct a technical equivalence assessment was not a unilateral requirement set by the Appellant but a mutually agreed condition for the data sharing. Indeed, the Agency itself has recognised in the Contested Decision that establishing technical equivalence can be in the interest of both parties involved in data sharing negotiations. The Agency stated that '*a mutual agreement to establish [technical equivalence] by an independent third party prior to data sharing for the purpose of an active substance under Article 95 of the BPR might very well be in the interest of the parties, particularly the Prospective Applicant, because it provides an indication whether the data under negotiation can actually be of use for their own substance. Therefore, in spite of the permission to refer granted with this decision, the parties are encouraged to continue their data sharing negotiations and to proceed with the [technical equivalence] assessment by the Institute as agreed earlier*'.

74. The Board of Appeal finds that, although the Agency might be correct in considering that the technical equivalence assessment is not a legal requirement for data sharing under the BPR, this legal observation cannot constitute an assessment of the parties' efforts to reach an agreement within the meaning of Article 63. On the contrary, it is part of the Appellant's and the prospective applicant's contractual freedom to insert a clause relating to a technical equivalence assessment in the data sharing agreement. As found by the Board of Appeal in paragraph 70 above, the decision to conduct the technical equivalence assessment as a pre-requisite to a data sharing agreement was not unilateral but had been agreed between the Appellant and the prospective applicant. Consequently, the Agency committed an error in finding that the Appellant did not make every effort when making the data sharing agreement conditional upon the performance of a technical equivalence assessment when the prospective applicant had explicitly agreed to such a condition.
75. The Contested Decision also states that the Appellant *'did not provide any justification for the unilateral breach of the contractual agreement and change of opinion or why the independent laboratory of their choice should no longer be suitable to establish the [technical equivalence]. [...] This change, which was not explained, shows a lack of reliability and consistency, and thereby constitutes a lack of efforts which resulted in the failure to reach an agreement'*.
76. The Board of Appeal observes however, having regard to the timeline of events, that, after the Appellant tested samples of the prospective applicant's commercially available active substance, the Appellant explained to the prospective applicant by emails of 30 June and 3 July 2014 that it considered the testing to be a preliminary step before sending its data to the technical equivalence consultant to make sure that the question of the impurities the Appellant had found in the samples acquired from the market would be addressed. The prospective applicant answered by an email of 8 July 2014 that it considered the Appellant's action to be a breach of contract. The prospective applicant further stated that it expected the Appellant to send the five batch analysis to the technical equivalence consultant by 24 July 2014.
77. On 23 July 2014, the Appellant informed the prospective applicant of the letter it had sent to the Agency and in addition told the prospective applicant that *'before [granting] the comparison of the 5-Batch-Analyses through [the technical equivalence consultant], it is important for us to clarify this issue [of the impurity] first'*. The Appellant also stated that *'due to the present circumstances an intensive check with regard to "chemical similarity" while taking into consideration of the discussed impurity seems to be necessary in advance'*.
78. The Board of Appeal notes that no further communication was sent by the prospective applicant to the Appellant after 23 July 2014 and before the data sharing dispute was lodged. On 6 November 2014, the Agency informed the Appellant that the prospective applicant had lodged a data sharing dispute on 23 October 2014.
79. In light of the above, the Board of Appeal observes that the Appellant justified on several occasions its reasons for requiring the technical equivalence assessment as a pre-requisite for the data sharing. When it performed a *'chemical similarity'* check before sending its five batch analysis for the technical equivalence assessment, the Appellant gave reasons for doing so to the prospective applicant. The Board of Appeal therefore finds that the Agency did not consider all the facts of the case in that it disregarded certain events when concluding that *'this change, which was not explained, shows a lack of reliability and consistency, and thereby constitutes a lack of efforts which resulted in the failure to reach an agreement'*. Consequently, the Agency erred in finding that the Appellant did not explain why it wished to clarify the issue of

impurities in advance. In fact, even though the Agency was correct in concluding that the Appellant, by unilaterally refusing to send the five batch analysis for the technical equivalence assessment, could be considered to have lacked reliability and consistency, this circumstance alone could not be interpreted as demonstrating a failure to make every effort.

80. The Board of Appeal further observes that, by its letter of 23 July 2014, the Appellant had left open the possibility of further discussion. However, the prospective applicant lodged the data sharing dispute with the Agency three months later, on 23 October 2014. This period of time was not used by the prospective applicant to advance the data sharing negotiations. Therefore, the negotiations between the parties could have progressed over this three-month period. The Agency erred in not taking this fact into account in a balanced assessment of whether both parties made *'every effort'*.
81. The Board of Appeal also observes that the Appellant addressed a letter to the Agency on 22 July 2014 explaining its reasons for requesting a technical equivalence assessment as a pre-requisite for data sharing and requesting the Agency to perform this assessment. On 1 August 2014, the Agency replied to the Appellant that *'[t]echnical equivalence or chemical similarity check are not legally required (nor relevant) for data sharing, and potential discrepancies between the reference source and an alternative source cannot be a justification to refuse sharing data'*. On 30 September 2014, the Appellant sent a letter to the European Commission asking whether a technical equivalence assessment should be performed as a pre-requisite for data sharing. On 2 October 2014, the European Commission answered that *'[it agreed] with [the Agency's] interpretation set out in the letter of 1 August 2014 in which it stated that technical equivalence or chemical similarity are not legal requirements for data sharing under Article 62 and 63 of the BPR'*.
82. The Board of Appeal notes that between 23 July 2014 and the submission of the data sharing dispute by the prospective applicant on 23 October 2014, the Appellant took steps to explain its approach and to have it confirmed by regulatory authorities. The Board of Appeal finds that the Appellant, in doing so, exercised care and diligence, which in turn constituted an effort within the meaning of Article 63 and that the Agency erred in its assessment in not taking these efforts into account.
83. In addition, during that period of time, the toxicologist reviewed, on behalf of the prospective applicant, the reports on the three studies owned by the Appellant which at that time constituted the object of the data sharing negotiations. The prospective applicant was informed by the Appellant that this review had taken place by an email sent on 11 August 2014. The Board of Appeal finds that this demonstrates that the Appellant was continuing to communicate with the prospective applicant as part of the data sharing negotiations.
84. In view of the above, the Board of Appeal observes that the Agency did not consider all the relevant facts in a balanced manner when assessing whether every effort had been made by the Appellant and the prospective applicant under Article 63. Having regard to the entirety of the negotiations, by disregarding some of the Appellant's efforts and by letting its own legal opinion that there was no need to perform a technical equivalence assessment influence the outcome of the Contested Decision, the Agency failed to assess the efforts of both parties in a balanced manner as required by Article 63(3).
85. The Board of Appeal therefore finds that the Agency made an error of assessment in finding that the Appellant had not made every effort to reach an agreement with the prospective applicant.

86. The fourth plea put forward by the Appellant should therefore be accepted and the Contested Decision annulled.
87. Since the Contested Decision has been annulled, it is not necessary to examine the Appellant's other pleas.

Consequences of the annulment of the Contested Decision

88. The Board of Appeal notes that, on 1 October 2015, the Agency informed the Board of Appeal that the prospective applicant had submitted a successful application under Article 95 for its active substance and '*would*' be included in the public Article 95 List shortly'. The Agency added that '*the data that the Data Applicant had submitted was sufficient for the Article 95 application without the need to rely on [the Agency's] (suspended) permission to refer to the Appellant's data*'. The Board of Appeal recalls that the Contested Decision indicated that '*[d]ata sharing had been sought for an application to be included on the Article 95 list as a supplier of an active substance that has not yet been approved*'. The Board of Appeal notes that the data the prospective applicant had requested from the Appellant were, according to the Agency's letter of 1 October 2015, no longer necessary for an inclusion in the Article 95 list, which was the purpose for which the prospective applicant had entered into data sharing negotiations and which lead to the data sharing dispute and the Contested Decision.
89. The Appellant claims that the Contested Decision has lost its purpose as a result of the Agency's decision to include the prospective applicant and its active substance in the Article 95 list.
90. The Board of Appeal finds that, as the change of circumstances and the consequences thereof did not form part of the initial appeal, the prospective applicant has had no possibility to be heard on this issue. As this question might affect the interests of the prospective applicant, the case is remitted to the Agency for it to examine whether, in light of the changed circumstances, a new decision is required.

Refund of the appeal fee

91. In accordance with Article 4(4) of Commission Implementing Regulation (EU) No 564/2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 19.6.2013, p. 17), the appeal fee shall be refunded if the decision is rectified in accordance with Article 93(1) of Regulation (EU) No 1907/2006 of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 1) or if the appeal is decided in favour of the appellant.
92. As the Board of Appeal has decided the appeal in favour of the Appellant the appeal fee shall be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls decision [CONFIDENTIAL] adopted by the Agency on 26 January 2015.**
- 2. Remits the case to the competent body of the Agency for re-examination.**
- 3. Orders the refund of the appeal fee.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal