EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

30 May 2017

(Substance evaluation – Admissibility – Direct concern – Downstream user – SIEF participant – New registrant)

Case number	A-022-2015
Language of the case	English
Appellant	Manufacture Française des Pneumatiques Michelin, France
Representative	Jean-Philippe Montfort and Thomas Delille Mayer Brown Europe-Brussels LLP, Belgium
Intervener	The German Member State Competent Authority Represented by: Federal Institute for Occupational Safety and Health, Germany
Contested Decision	Decision of 29 May 2015 on the substance evaluation of N,N- dicyclohexylbenzothiazole-2-sulphenamide adopted by the European Chemicals Agency pursuant to Article 46(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the dispute

1. On 10 November 2015, the Appellant lodged the present appeal at the Registry of the Board of Appeal against the Contested Decision on a substance evaluation of N,N- dicyclohexylbenzothiazole-2-sulphenamide (CAS No 4979-32-2; EC No 225-625-8; hereinafter the 'Substance') adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 46(1) of the REACH Regulation (all references to Articles, Recitals, Titles, Chapters and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

2. Under point II.3 of the Contested Decision, the Agency requested that the addressees of the Contested Decision (hereinafter the 'addressees of the Contested Decision') submit by 7 March 2017 inter alia an updated chemical safety report (hereinafter the 'CSR') containing further information on environmental exposure assessment, namely:

   (a) Assumptions underlying the environmental exposure estimation;

   (b) Environmental exposure assessment for the sediment compartment from manufacturing the Substance;

   (c) Environmental exposure assessment for the production and use of tyres and general rubber products;

   (d) Environmental releases from the use of tyres.

Background to the dispute

3. The Appellant is a downstream user of the Substance. It uses the Substance, which is an accelerator of vulcanisation for certain types of rubber compounds, in the manufacture of internal components of tyres.

4. The Substance was included in the Community rolling action plan ('CoRAP') for substance evaluation for 2013 due to the initial grounds for concern relating to its carcinogenic and mutagenic properties, toxicity to reproduction, sensitising properties and PBT/vPvB properties. In relation to exposure, the Member State Committee (hereinafter the 'MSC') noted that the Substance has a wide dispersive use, is used by consumers and that workers are exposed to it.

5. The German Member State Competent Authority (hereinafter the 'German MSCA') was appointed to carry out the evaluation.

6. On 17 May 2013, the lead registrant for the Substance contacted the Appellant to request its support during the substance evaluation process. The lead registrant requested the Appellant, inter alia, to assist in that process by providing a statement showing that '*[the Substance] is predominantly used in bonding compound and / or inner part of [tyres] where mechanical [tyre] abrasion does not take place*' and that '*[s]ubsequently a pollution with [the Substance] containing [tyre] wear particles should be of minor importance for a risk characterisation.*'

7. On 24 May 2013, the European Tyre and Rubber Manufacturers' Association (hereinafter 'ETRMA') issued a statement according to which '*[i]t is common practice in the tyre industry, that [the Substance] is used in the formulation of interior tyre components […], while its use in tyre tread compounds is negligible.*' The statement also specified that '*at the elevated temperatures of the tyre curing process, the vulcanization reaction with sulphur consumes [the Substance] which undergoes a chemical transformation into different molecular fragments.*' The ETRMA statement also summarised the conclusions of an industry project showing that an accelerator substance similar to the Substance could not be detected in the debris of tyre road wear particles. The statement concluded that '*[it believed that] any concern on the*

exposure of [the Substance] to the environment as a consequence of tyre wear debris is negligible' and that ETRMA considered grounds for concerns associated with exposure, the wide dispersive use, and the use of the Substance by consumers to be unjustified.

8. On 29 April 2014, the Agency notified a draft decision (hereinafter the 'Draft Decision') prepared by the German MSCA according to Article 46(1) to the addressees of the Contested Decision and invited them, pursuant to Article 50(1), to provide comments within thirty days. The Draft Decision requested further information to clarify potential concerns relating to the persistent, bioaccumulative and toxic or very persistent and very bioaccumulative (hereinafter 'PBT/vPvB') properties of the Substance and its wide dispersive use. Additionally, the Draft Decision stated that '*[a]lthough the registrants focused on the use of tyres due to low abrasion of general rubber goods compared to that of tyres which can be regarded as worst case, the amounts of [the Substance] used for the production and use in tyres need to be further specified. Therefore, pursuant to Article 46(1) […] the registrants are requested to specify the term "general rubber products" and to report the amounts used for the production of tyres and that of general rubber goods separately […].*'

9. On 15 May 2014, the lead registrant addressed a message to the Appellant and to ETRMA requesting the latter to specify the meaning of the term '*general rubber products*' and to report separately how much of the Substance is used in the production of tyres and in the production of general rubber products.

10. On 23 May 2014, the lead registrant addressed a message to ETRMA and the Appellant requesting their assistance to support the lead registrant's assumption of '*zero-emission [of the Substance] during life-cycle of the [tyre] (e.g. 100% decomposition of [the Substance] during vulcanization)'* and reiterated the request for a statement about the amounts of the Substance used respectively in the tyre sector and for general rubber products.

11. On 6 June 2014, the lead registrant submitted comments on the Draft Decision describing, inter alia, that '*[the Substance] as a vulcanisation accelerator is completely consumed during the vulcanisation process […]'* and '*in an updated dossier, the Registrant will present additional information for the percentage of [the Substance] used in General Rubber Goods.*' The German MSCA considered the lead registrant's comments and amended the Draft Decision (hereinafter the 'amended Draft Decision'), by adding the statement that '*[i]n his comments, the Registrants [sic] gave further information regarding production and use of tyres and general rubber products. The [German MSCA] agrees with the Registrants that the scenario for the use of tyres for which most of the [Substance] is used represents a worst case. The request for two separate scenarios will no longer be part of the [Draft Decision]*.' The amended Draft Decision however maintained the information request for a revised version of the CSR containing further information on environmental exposure assessment. The German MSCA notified the amended Draft Decision to the Competent Authorities of the other Member States (hereinafter 'MSCAs') and the Agency on 30 October 2014 requesting proposals for amendment (hereinafter 'PfAs') pursuant to Article 51(2) in conjunction with Article 52(2). Two MSCAs and the Agency submitted PfAs.

12. On 5 December 2014, the Agency notified the PfAs to the addressees of the Contested Decision and invited them to provide comments within thirty days in accordance with Articles 52(2) and 51(5).

13. On 15 December 2014, the Agency referred the amended Draft Decision to the MSC.

14. On 2 January 2015, the lead registrant provided comments on the PfAs. It stated inter alia that '*[the Substance is] […] a vulcanisation accelerator which is completely consumed and destroyed during the vulcanisation process and […] almost exclusively […] used in inner parts of tyres which are not subject to abrasion.*' The MSC took comments of the addressees of the Contested Decision on the PfAs into account.

15. On 22 January 2015, the lead registrant sent a message to the Appellant containing an excerpt from the amended Draft Decision consisting of the required information and the statement of reasons for the further information requested on the environmental exposure assessment.

16. From 3 to 5 February 2015, the MSC met. Two representatives of the addressees of the Contested Decision participated as observers at the meeting. On 5 February 2015, the MSC reached unanimous agreement regarding the Contested Decision including modifications to the amended Draft Decision. The modifications included that '*[i]n exposure scenario 5 (use of tyres and general rubber products) the Registrant(s) assume […] [the] complete consumption [of the Substance] during vulcanisation. However, [this] does not seem plausible […]. Therefore, it is expected that residues of [the Substance] will still be contained in the product and will be potentially released to the environment via abrasion during use and the following processes in the environment (leaching, degradation of particles, etc.)*'. The amended Draft Decision was further modified to include that '*[p]ursuant to Article 46(1) […] the Registrant(s) are requested to update the exposure scenario for the use of tyres on a (realistic) worst case basis*.'

17. On 26 March 2015, the Appellant contacted the lead registrant to explain that it had decided to register the Substance and expressed '*its willingness to enter into an agreement to join the substance information exchange forum for the Substance*' (hereinafter the 'SIEF agreement').

18. On 23 April 2015, the Appellant signed the SIEF agreement.

19. On 29 May 2015, the Agency adopted the Contested Decision in accordance with Article 51(6).

20. On 10 August 2015, the lead registrant sent a copy of the Contested Decision to the Appellant.

21. On 11 August 2015, the Agency published a non-confidential version of the Contested Decision on its website.

22. On 28 August 2015, the Appellant signed a '*declaration of accession*' to the Sulfenamide/Thiazole Consortium (hereinafter the 'S&T Consortium') established in 2009 by the addressees of the Contested Decision.

23. On 29 September 2015, the Appellant submitted as only representative for two non-EU companies the registration dossiers for the Substance to the Agency. On 19 October 2015, the Appellant received a notification from the Agency that its registration of the Substance was successful.

Procedure before the Board of Appeal

24. On 10 November 2015, the Appellant lodged the present appeal at the Registry of the Board of Appeal.

25. On 30 November 2015, the Agency requested an extension of the time limit for submitting its Defence. On 9 December 2015, the Chairman of the Board of Appeal granted the Agency a time extension to lodge its defence '*covering any admissibility and substantive issues that may be present in the appeal case*'.

26. On 12 February 2016, the Agency submitted Observations on Admissibility requesting the Board of Appeal to dismiss the appeal as inadmissible and stating that it '*reserved the right to submit observations on the merits of the Appeal*.'

27. On 16 February 2016, the German MSCA applied for leave to intervene in the proceedings before the Board of Appeal in support of the Agency. By decision of 15 March 2016, the Board of Appeal, having heard the Parties, granted the application to intervene.

28. On 10 May 2016, the Appellant submitted its response to the Agency's Observations on Admissibility and responded to the questions from the Board of Appeal. On the same day, the German MSCA lodged its Statement in Intervention.

29. On 27 June 2016, the Appellant submitted its Observations on the Statement in Intervention. On the same day, the Agency submitted its Observations on the Appellant's reply to the Agency's Observations on Admissibility, and its Observations on the Statement in Intervention.

30. On 12 July 2016, the Appellant informed the Registry of the Board of Appeal that it '*reserved the right to contest the admissibility and/or soundness of [the Agency's Observations on Admissibility and the Agency's Observations on the Statement in Intervention]*'.

31. On 15 August 2016, the Board of Appeal informed the Appellant that it had decided to allow the Appellant to submit comments on the Agency's Observations on the Statement in Intervention.

32. On 15 September 2016, the Appellant submitted its comments on the Agency's Observations on the Statement in Intervention.

33. The written procedure was closed on 21 September 2016. In view of the Appellant's and the Agency's requests for a hearing to be held, and pursuant to Article 13 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, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; hereinafter the 'Rules of Procedure'), the Parties were summoned to a hearing, which took place on 20 December 2016. At the hearing, the Parties and the Intervener made oral submissions and responded to questions from the Board of Appeal.

Forms of order sought

34. In its Notice of Appeal, the Appellant requests the Board of Appeal to:

- annul Part III Section 3 Points a), c) and d) of the Contested Decision; or, alternatively
- amend the statement of reasons in Part III Section 3 of the Contested Decision as follows:

'*3. Further information on environmental exposure assessment*

DCBS is a potential PBT-/vPvB-substance produced in amounts greater than 1000 tonnes per year and is ~~considered~~ possibly a substance with wide dispersive uses (production and uses of tyres and rubber products).

[…]

d) Environmental releases from the use of tyres

In exposure scenario 5 (use of tyres and general rubber products) the Registrant(s) assume the concentration of DCBS in articles to be […] % due to complete consumption during vulcanisation. However, a concentration of […] % in tyres ~~does not seem to be plausible~~ ~~when it is referred to a concentration of DCBS in preparations of up to […] in ES 2 and 4 (production of tyres and general rubber products, retreading), especially when process temperatures do not exceed 200 °C. (as stated by the Registrants) but according to the registrations the decomposition temperature of DCBS accounts for 300 °C at 1013 hPa~~ has to be demonstrated.

~~Therefore~~ it is ~~expected~~ suspected that residues of DCBS ~~will~~ may be still contained in the product and ~~will~~ may be potentially released to the environment via abrasion

during use and the following processes in the environment (leaching, degradation of particles, etc.).

As already stated above, due to a read-across to CBS, the Registrant(s) did not perform exposure estimations for DCBS itself. However, the assumptions and (possible) input data need to be ~~plausible~~ completed. Moreover, ~~a concentration of […] % cannot be regarded as a worst case consideration and~~ further reliable information is required on a be [sic] concentration of […] % to regarded [sic] as a worst case consideration.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) are requested to update the exposure scenario for the use of tyres with the relevant information on ~~a (realistic)~~ the worst case scenario ~~basis~~.

In their comment on the draft decision, the Registrant(s) agreed to update the CSR considering further information on environmental releases from the use of tyres.'

- order the refund of the appeal fee.

35. The Agency requests the Board of Appeal to dismiss the appeal as inadmissible in its entirety.

36. The Intervener requests the Board of Appeal to dismiss the appeal in its entirety.

Reasons

37. The Appellant raises two pleas in law. By its first plea, which consists of two parts, the Appellant alleges that the Agency breached Article 46 and went beyond its margin of discretion (i) by failing to carefully and impartially examine the facts of the case and (ii) by failing to ensure that the requested information on exposure for the use of the Substance in tyres is obtained from the relevant downstream users. By its second plea, the Appellant argues that the Agency should have conducted a compliance check prior to the substance evaluation to request the information required in the Contested Decision.

38. The Agency challenges the admissibility of the appeal. In particular, the Agency submits that the Contested Decision has only remote effects on the legal situation of downstream users and new registrants of the Substance and that these remote effects do not demonstrate the Appellant's direct or individual concern vis-à-vis the Contested Decision.

39. The Agency also raises doubts concerning the date at which the Contested Decision became known to the Appellant and whether the appeal was correctly lodged within the time limit laid down in Article 92(2).

40. The Appellant challenges the admissibility of the Agency's and the Intervener's substantive arguments raised respectively by the Intervener in its Statement in Intervention and by the Agency in its Observations on the Statement in Intervention.

41. In order to frame the examination of this appeal and the arguments to be considered, the Board of Appeal will first examine the Appellant's objections as to the admissibility of the Agency's and the Intervener's substantive arguments.

42. The Board of Appeal will, second, examine the Agency's objection to the admissibility of the appeal as a whole, which is based on the alleged lack of legal standing of the Appellant. In that context, the Board of Appeal will start by examining the second part of the first plea, by which the Appellant argues that the Agency had an obligation to involve downstream users in the substance evaluation process. The Board of Appeal considers that the Appellant's argument, if accepted, would mean that the substance evaluation procedure includes procedural rights for the downstream users. Should the substance evaluation procedure include procedural rights for the downstream users which were not taken into account in the procedure leading to the adoption of the

Contested Decision, this circumstance on its own would provide to the Appellant legal standing to challenge a decision that affects its procedural rights (see judgment of 18 November 1992, *Rendo and Others* v *Commission,* T-16/91, EU:T:1992:109, paragraphs 51 to 56). The Board of Appeal will then examine whether the present appeal is admissible on other grounds, in particular whether the Appellant has demonstrated that the Contested Decision is of direct and individual concern to it.

Admissibility of the Agency's and the Intervener's substantive arguments

Arguments of the Parties

43. As noted in paragraph 26 above, the Agency submitted Observations on the Admissibility of the Appeal on 12 February 2016 in which it stated that it reserved the right to submit observations on the merits of the appeal. The Appellant opposes this statement from the Agency and argues that this is in breach of Article 7(2)(b) of the Rules of Procedure, which provides that the Agency's Defence shall contain '*the pleas in law and the arguments of fact and law relied on*' and Article 12(2) of the Rules of Procedure which provides that '*[n]o new pleas in law may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that it is based on new matters of law or of fact that come to light in the course of the proceedings.*'

44. The Appellant further emphasises that the Board of Appeal, when extending the deadline to lodge the defence, had specifically requested the Agency to prepare its defence covering any admissibility and substantive issues that may be present in the appeal. The Appellant requests the Board of Appeal to rule that the Agency's Observations on Admissibility constitute a defence and that the Agency should not be able to develop any new plea in law not contained in that submission.

45. The Appellant argues further that the Agency's substantive arguments contained in its Observations on the Statement in Intervention are inadmissible because the Agency's Observations on Admissibility constitute its sole defence. The Appellant claims that the Agency sought to use its Observations on the Statement in Intervention as a means to make the substantive arguments that it had failed to make previously in the appeal proceedings. The Appellant adds that the Agency's substantive arguments are inadmissible as they were based on the arguments put forward by the Intervener in its Statement in Intervention, which were themselves inadmissible because they breached Article 8(3) of the Rules of Procedure and went beyond the scope of supporting the remedy sought by the Agency in its Observations on Admissibility, which requested solely that the appeal be considered inadmissible.

46. The Appellant claims additionally that, should the Board of Appeal decide that the present appeal is admissible and that the Agency's and the Intervener's substantive arguments are inadmissible, the Board of Appeal should then decide in favour of the Appellant on the forms of order it seeks.

47. The Agency disputes the Appellant's arguments. It argues that the Notice of Appeal was clearly inadmissible and that it is only in such very exceptional circumstances that it considers limiting its first submission to the issues of admissibility. It claims that it followed this practice in one previous appeal without objections from the Board of Appeal.

48. The Agency adds that the present appeal is mainly about admissibility and that it chose this two-stage approach for reasons of procedural economy and that it acted in good faith. It also states that it was not aware of any limitations as to the scope of the arguments it could make when preparing the Observations on the Statement in Intervention.

Findings of the Board of Appeal

49. With regard to the Appellant's claim that the arguments on the merits of the case raised by the Agency in its Observations on the Statement in Intervention and by the Intervener in its Statement in Intervention are inadmissible, the Board of Appeal notes that Article 7(1) of the Rules of Procedure requires that *'[t]he Agency shall lodge the defence within two months after service of the notice of appeal'* but that *'[t]he Chairman may, in exceptional circumstances, extend that time limit on a reasoned application by the Agency.*'

50. On 9 December 2015, applying Article 7(1) of the Rules of Procedure, the Chairman of the Board of Appeal granted the Agency, further to its reasoned request, an extension of the time-limit to lodge its defence. The letter informing the Agency of the extension requested the Agency to '*prepare its defence covering any admissibility and substantive issues that may be present in the appeal case, also taking into account Article 11(2) of the Rules of Procedure'.* The Agency subsequently lodged Observations on Admissibility which consisted of arguments pertaining to the Appellant's lack of direct and individual concern in challenging the Contested Decision, called into question whether the appeal was brought within the three-month time-limit set out in Article 92(2), and requested the Board of Appeal to dismiss the appeal as inadmissible while reserving the '*right to submit observations on the merits of the Appeal*.'

51. The Board of Appeal observes that the Agency, in reserving the right to submit observations on the merits of the appeal, acted contrary to the express wording of the Chairman's decision which specifically requested the Agency to lodge a defence covering both admissibility and substantive issues. The Agency only provided substantive arguments at a later date in its Observations on the Statement in Intervention.

52. The Agency claims that it followed this approach as the present appeal concerns primarily questions of admissibility and that it therefore considered a two-stage approach appropriate.

53. The Board of Appeal notes that Article 93(2) provides that the '*Chairman of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed in accordance with Article 92(2). In the affirmative, the appeal shall be remitted to the Board of Appeal for examination of the grounds*.'

54. Article 11(2) of the Rules of Procedure provides that '*[i]f the Chairman does not decide on the admissibility of the appeal within the time limit laid down in Article 93(2) […] [i.e. thirty days], the appeal shall be remitted to the Board of Appeal for examination of the grounds and the admissibility. The decision on admissibility shall form part of the final decision*.'

55. The Board of Appeal observes that the Rules of Procedure do not establish a two-stage procedure whereby the Agency may first lodge a submission objecting to the admissibility of an appeal, followed by a separate submission on the substance of a case. The Rules of Procedure, on the contrary, only foresee that a full defence is submitted by the Agency within two months, which may, as was the case in this appeal, be extended in exceptional circumstances. The Agency's argument according to which it was allowed to lodge its substantive arguments on the appeal in a separate document from its defence must therefore be rejected.

56. As a consequence, the Board of Appeal finds that the Agency's substantive arguments submitted in its Observations on the Statement in Intervention cannot be admitted as they were submitted after the extended deadline for the defence. The Board of Appeal observes additionally that if it were to consider the Agency's substantive arguments

this would result in the Agency benefitting from its own unauthorised choice of submitting a defence covering only admissibility and not the substance of the appeal.

57. The Appellant also claims that the Intervener's substantive arguments are inadmissible. The Board of Appeal will therefore consider the admissibility of the substantive arguments submitted by the Intervener in its Statement in Intervention.

58. The Board of Appeal notes that Article 8(3) of the Rules of Procedure, in the version in force at the time of the submission of the Statement in Intervention, provides that '*[t]he intervention shall be limited to supporting or opposing the remedy sought by one of the parties*'.

59. As Article 8(3) of the Rules of Procedure mirrors Article 40 of the Statute of the Court of Justice, the case-law of that Court concerning the latter provision should be applied by analogy to the former.

60. The Court of Justice has held that an intervener may advance its own arguments, but only to the extent that they support the remedy requested by the party in whose support it is intervening (see judgment of 21 December 2011, *Commission* v *Austria*, C-28/09, EU:C:2011:854, paragraph 50, and the case law cited therein). In addition, according to the case-law, an intervener may not adduce arguments that alter the framework of the dispute as defined by the applicant (see judgment of 13 April 2005, *Verein für Konsumenteninformation* v *Commission*, T-2/03, EU:T:2005:125, paragraphs 51 to 53, and the case law cited therein) or introduce new pleas (see judgment of 3 April 2003, *BaByliss* v *Commission*, T-114/02, EU:T:2003:100, paragraphs 417 and 418, and the case law cited therein).

61. In the present case, the Agency requested in its Observations on Admissibility that the Board of Appeal '*dismiss the appeal as inadmissible in its entirety.*' The Intervener submitted however that '*the appeal should be dismissed as inadmissible and unfounded*' and advanced substantive arguments in support of the latter request. However, the Intervener acknowledged that '*to our knowledge [the Agency] so far has not submitted observations on the substance and the pleas in law of the [Notice of Appeal].*'

62. The Board of Appeal finds, by analogy with the procedure of the EU Courts, that an intervener supporting the Agency is not entitled to seek to have an appeal dismissed as unfounded, and to make substantive arguments in support of its intervention, when the Agency has only raised an objection of inadmissibility.

63. The Board of Appeal therefore concludes that the Intervener's arguments on the substantive issues in the case are inadmissible because they extend beyond the form of order sought by the Agency in its Defence.

64. The Appellant also argues that, should the appeal be considered admissible, the appeal should be decided in its favour if the substantive arguments of the Agency and the Intervener are deemed to be inadmissible. In essence, the Appellant is requesting the Board of Appeal to adopt a decision by default.

65. The Board of Appeal observes in that regard that Article 7(3) of the Rules of Procedure specifies that '*[w]here the Agency, despite being duly summoned, fails to lodge a defence, the proceedings shall continue without a defence*.'

66. In any case, the Agency submitted its Observations on Admissibility within the time-limit set for the defence and in the proper form. This submission and the Agency's claims concerning the admissibility of the appeal must therefore be examined by the Board of Appeal. The Board of Appeal will however not examine the Agency's substantive arguments that were lodged after the deadline set for the defence and the Interveners substantive arguments in the Statement in Intervention.

Admissibility of the appeal

67. As a preliminary point, the Board of Appeal will address the Appellant's argument concerning its legal standing for this appeal as a downstream user in the substance evaluation procedure. As set out in paragraph 42 above, should the substance evaluation procedure entail rights for downstream users, this circumstance on its own could give the Appellant legal standing to challenge a decision that affects its procedural rights.

Legal standing of downstream users – The alleged obligation to request information from the downstream users (second part of the Appellant's first plea)

Arguments of the Parties

68. In support of the second part of its first plea, the Appellant argues that whilst the operative parts of the REACH Regulation only require registrants to provide the information requested in a substance evaluation decision, Recital 66 provides that '*[t]he Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to human health or the environment*.'

69. The Appellant claims that this Recital reflects the objectives of substance evaluation and confirms the role of downstream users as potential providers of the information necessary and adequate to clarify a concern identified in a substance evaluation decision.

70. The Appellant concludes that downstream users should therefore have access to the appeals process regardless of whether the registrants of a substance subject to a substance evaluation decision have appealed it. The Appellant considers that this should be the case at least for the parts that affect downstream users, provided that they can demonstrate how that part of the substance evaluation decision affects them.

71. The Appellant further develops this argument in alleging a failure by the Agency to ensure that the requested information on exposure from the use of the Substance in tyres is obtained from the relevant downstream users. It argues that although Articles 46(1) and (2) only refer to registrants as the addressees of an information request in a substance evaluation decision, there is a duty on competent authorities and the Agency to ensure that the registrants adequately provide in their dossier information that was communicated to them by downstream users.

72. The Appellant argues further that while the mention of downstream users in Articles 50(1) and 51(5) probably refers to them being potential addressees of evaluation decisions when they submit testing proposals, Article 52(1), which is placed under the Title '*adoption of decisions under substance evaluation*', provides that '*[t]he competent authority shall circulate its draft decision in accordance with Article 46, together with any comments by the registrant or downstream user, to the Agency and to the competent authorities of the other Member States*.' The Appellant is of the opinion that this provision clearly implies that downstream users must be given an opportunity to comment on draft decisions directly in the course of a substance evaluation that concerns them.

73. The Agency argues that the REACH Regulation, in the registration and evaluation regimes, places most of the burden to generate, collect and assess hazards and exposure information on manufacturers, importers and only representatives, and that downstream users will be impacted by these activities.

74. The Agency also argues that the REACH Regulation provides certain mechanisms to protect the interests of downstream users. The Agency explains in particular that downstream users have the right to submit information to registrants for consideration

when registrants carry out their chemical safety assessment. The Agency explains that downstream users can prepare a chemical safety report if they disagree with the one prepared by the registrant for relevant uses.

75. However, the Agency takes the view that the rights and obligations of addressees of a substance evaluation decision and those of downstream users and new registrants are different. According to the Agency, these differences justify why only the addressees of a substance evaluation decision have the right to appeal such a decision.

76. The Intervener argues that, in accordance with Article 46(1), substance evaluation decisions are addressed only to registrants. The Intervener acknowledges that the registrants may not always be in the position to provide the required information if it lies with downstream users but adds that Articles 50(1) and 51(5) give downstream users the possibility to provide information. The Intervener also recognises that if the requested information concerns data which can only be provided by downstream users, close collaboration between the registrants and the downstream users is required to enable registrants to fulfil their obligations.

Findings of the Board of Appeal

77. The Appellant claims that the Agency breached Article 46 and exercised its margin of discretion incorrectly by failing to seek out and involve downstream users in the substance evaluation process and the decision-making procedure.

78. The Board of Appeal observes that the Appellant is in essence claiming that the Contested Decision affects its procedural rights as a downstream user and that these procedural rights were breached in the preparation of the Contested Decision. The Appellant, following this reasoning, would therefore have standing to challenge the Contested Decision. If this reasoning were found to be correct, the present appeal would be, as observed in paragraph 42, admissible for this reason alone. It is therefore appropriate for the Board of Appeal to examine this claim before the other admissibility issues in the present appeal.

79. The Board of Appeal observes that the framework of duties for downstream users under the REACH Regulation places obligations upon them in specific situations.

80. First, Article 37(1) states that '*a downstream user […] may provide information to assist in the preparation of a registration'.* This provision does not place any obligation on downstream users but offers them a possibility to assist in the registration of a substance. Article 37(2) further details this possibility as '*a right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a mixture with the aim of making this an identified use*' and states that '*[d]istributors shall pass on such information to the next actor or distributor up the supply chain.'* This is a 'right' and not an obligation and means that once a downstream user has made use of the possibility to identify a use of a substance to its supplier, the supplier then has an obligation to provide this information to the next actor up the supply chain.

81. Second, under Article 37(4) downstream users have an obligation, except for certain listed exceptions, to prepare a chemical safety report '*for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to [them] in a safety data sheet or for any use [their suppliers advise against].'* If the downstream user's use does not fall outside the conditions described in its supplier's exposure scenario, the downstream user does not have an obligation to prepare a CSR. Furthermore, pursuant to Article 38(1), a downstream user only has an obligation to report information to the Agency if it has to prepare a chemical safety report in accordance with Article 37(4) or if it is relying on the exemptions in Article 37(4)(c) or (f). It follows from this that a downstream user only

has an obligation to report information to the Agency pursuant to Article 38 in these situations.

82. In the present appeal, the Contested Decision describes the use of the Substance in tyres and general rubber products as falling under Exposure Scenarios 2 and 5 as detailed by the lead registrant in its registration dossier. The Appellant stated in its response to the Agency's Observations on Admissibility that '*there was no obligation on the Appellant to report to ECHA information under Article 38 of REACH. Indeed, the uses that the Appellant makes of the Substance falls under the conditions outlined in the Exposure Scenarios (ES2 and ES5) as communicated by its EU supplier in its extended Safety Data Sheet*'. The Appellant was therefore under no obligation to prepare and submit additional information or to prepare its own CSR.

83. The Board of Appeal therefore concludes that the Contested Decision correctly placed the obligation to submit further information on Exposure Scenarios 2 and 5 solely on the registrants.

84. The Board of Appeal observes that, as described in paragraphs 68 to 72 above, the Appellant also draws conclusions as to the necessity of the participation of downstream users to the substance evaluation process from a reading of Articles 46(1), 46(2), 50(1), 51(5) and 52(1).

85. The Board of Appeal observes that Article 46(1) describes the procedure by which competent authorities prepare draft decisions requiring registrants to submit further information under substance evaluation and lays down that '*[i]f the competent authority considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission.*' Article 46(2) states that '*[t]he registrant shall submit the information required to the Agency by the deadline set.'* This Article does not mention downstream users.

86. Article 50 forms part of Chapter 4, '*Common provisions*', of Title VI, which concerns '*Evaluation*'. Article 50(1) states that '*[t]he Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency.'* This Article therefore concerns registrants and downstream users' rights under the whole evaluation framework, which includes testing proposals under Article 40, compliance checks under Article 41, and substance evaluation under Article 46. The Board of Appeal finds that the term '*concerned'* in Article 50 therefore refers to registrants or downstream users insofar as they are recipients of a draft decision either under the compliance check, testing proposal or substance evaluation procedures. It cannot be read as meaning that downstream users have rights with regard to every decision taken under the evaluation framework, only those where they are a '*concerned*' registrant or downstream user.

87. Article 52(1) provides that '*[t]he competent authority shall circulate its draft decision in accordance with Article 46, together with any comments by the registrant or downstream user, to the Agency and to the competent authorities of the other Member States.*'

88. The Board of Appeal observes that Article 52, unlike Article 50, does not contain the term '*concerned*' before the term '*downstream user*'. The Board of Appeal considers however that this is not an indication, as the Appellant claims, that all downstream users of a substance have a right to comment on draft evaluation decisions concerning that substance. Article 52 must be understood as a continuum of the procedure described in Articles 50(1) and 51(5). That is, once a '*concerned*' downstream user or registrant has submitted comments to the Agency, the comments provided by that downstream user are to be circulated. The adjective '*concerned'* need not be used in

Article 52 as the person who provided comments is already known. It follows that Article 52(1) does not increase the number of downstream users entitled to submit comments on an evaluation decision.

89. For the reasons set out in paragraphs 85 to 88 above, the Board of Appeal finds that requests for further information under substance evaluation do not extend to downstream users in general. The request for further information may extend to concerned downstream users in certain cases, for example where the substance evaluation decision covers uses for which a downstream user report has been notified to the Agency under Article 38(1).

90. As regards Recital 66, also cited by the Appellant to justify the involvement of downstream users in the substance evaluation process, the Board of Appeal considers that whilst a recital in the preamble to a regulation may cast light on the interpretation to be given to a legal rule, it cannot in itself constitute such a rule (see judgment of 13 July 1989, *Casa Fleischhandels v Bundesanstalt für landwirtschaftliche Marktordnung*, C-215/88, EU:C:1989:331, paragraph 31). The Board of Appeal therefore concludes that Recital 66 cannot on its own create an obligation for the Agency to request downstream users to provide information on the substance being evaluated.

91. In the present case and as observed in paragraph 82 above, the Appellant has not prepared its own CSR in accordance with Article 37(4) or provided a downstream user report to the Agency pursuant to Article 38. Therefore, the Agency and the German MSCA correctly applied the relevant provisions of the REACH Regulation in that there was no obligation to involve the Appellant in the substance evaluation process or the decision-making procedure. It follows that the procedural rights of the Appellant were not breached in the preparation and adoption of the Contested Decision.

92. It follows that the Appellant does not have legal standing to challenge the Contested Decision based on the alleged infringement of its procedural rights as a downstream user.

93. The Board of Appeal also finds that it is not the responsibility of the Agency or an evaluating Member State competent authority to seek out and identify downstream users that may be interested in a substance evaluation decision.

94. The provisions of the REACH Regulation envisage communication in supply chains on the risks of substances and place this responsibility both on registrants and downstream users. This objective is stated clearly in Article 1(3), which provides that '*[t]his Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.*' Recitals 56, 59 and 60 and the provisions under Titles IV and V further explain and give substance to this objective. These provisions foresee the downstream users' active role under the REACH Regulation to make their uses and the related risks known to registrants. The Board of Appeal observes additionally that given the very large number of downstream users that are part of complex and extensive supply chains, it would be administratively impractical for the Agency and the Member State competent authorities to identify and contact them individually to verify the statements provided by registrants related to the uses of substances. The duty to ensure that information on uses and related risks is accurate is necessarily one that is largely incumbent on actors in the supply chains themselves.

95. The Board of Appeal concludes therefore that the Agency did not breach Article 46 by failing to seek out and involve downstream users in the substance evaluation process and the decision-making procedure, and that second part of the Appellant's first plea is rejected.

96. The Board of Appeal will next examine whether the present appeal is admissible on other grounds, in particular whether the Appellant has demonstrated that the Contested Decision is of direct and individual concern to it.

Direct concern

Arguments of the parties

97. The Agency, supported in this respect by the Intervener, claims that the Contested Decision does not affect the Appellant's legal situation directly. It argues that the Appellant only lists '*unsubstantiated factual impacts and hypothetical future and indirect legal effects that are insufficient to demonstrate any direct concern'.*

98. The Agency considers that the possibility to market the Substance is not likely to be affected by the Contested Decision. According to the Agency, the addressees of the Contested Decision have decided to collect the required information rather than to cease manufacturing the Substance.

99. The Agency adds that the addressees of the Contested Decision have no authority under the REACH Regulation to compel the Appellant to provide the requested information. The Appellant is under no obligation to update its CSR as it has already complied with its obligations under Article 37(1) by identifying its use of the Substance. The Agency also notes that by arguing that it would have to prepare its own downstream user report, the Appellant rejects in advance the result of the environmental exposure assessment required by the Contested Decision.

100. The Agency argues, moreover, that the data sharing rules in the REACH Regulation are limited to the data required in the context of registration, which excludes environmental exposure data. Therefore, insofar as they are requested to provide information on environmental exposure, the addressees of the Contested Decision have no obligation to request such information from downstream users as this information does not consist of tests carried out on vertebrate animals. The Agency further notes that the Appellant was not yet a registrant of the Substance at the time of the Contested Decision. It therefore had no obligation to update its CSR or safety data sheet (hereinafter the 'SDS') in consequence of the Contested Decision. Therefore, the Appellant was not directly concerned by the Contested Decision at the relevant point in time.

101. The Appellant argues that it satisfies the requirements of the direct concern criterion set out in the case law of the European Union Courts, namely that a contested measure is capable of producing effects that directly affect the legal situation of the person concerned and that the contested measure leaves no discretion to its addressees, their implementation being purely automatic without the application of other intermediate rules.

102. First, the Appellant argues that the Contested Decision does not leave any discretion to its addressees because it requires them to provide the requested information without the application of any other intermediate rules.

103. Second, the Appellant argues that its legal situation is directly affected by the Contested Decision because of its position as a downstream user, as a new registrant of the Substance and as a SIEF participant.

104. The Appellant argues that its legal situation as a downstream user is directly affected by the Contested Decision because its uses are covered by Exposure Scenarios 2 and 5, which concern the production of tyres and general rubber products and the use of tyres and general rubber products respectively. The Appellant argues in particular that, as a downstream user, it will be required to provide the addressees of the Contested Decision with part of the information requested in the Contested Decision for the

environmental exposure assessment as regards the production and use of tyres and general rubber products and environmental releases from the use of tyres.

105. The Appellant also argues that, as a downstream user, it will bear the consequences of the evaluation of the information provided by the addressees of the Contested Decision, such as any new risk management measures, and that it will bear part of the costs incurred in the generation of the required information in the likely event that the addressees of the Contested Decision raise the purchase price of the Substance to factor in those costs. The Appellant also claims that it would be directly affected as a downstream user if the addressees of the Contested Decision decided, as a result of the Contested Decision, to stop manufacturing the Substance. The Appellant also claims that it would be directly affected if, as a result of the substance evaluation, the German MSCA initiated authorisation or restriction procedures for the Substance. The Appellant adds that the Contested Decision raises concerns about the Appellant's use of the Substance, which impacts on the perception and 'marketability' of the Appellant's tyres which are made using the Substance.

106. The Appellant also submits that the Contested Decision directly affects its legal situation as it triggers the duty for registrants to update their CSR and, as a consequence, their SDS. The Appellant considers that it has an obligation to provide sufficient information to the registrants to enable them to update the exposure scenarios for the Substance's use in tyres. The Appellant claims that it is also under the obligation to prepare its own CSR for the Substance.

107. The Appellant explains in that regard that Exposure Scenarios 2 and 5 were developed by the lead registrant on the basis of information provided by ETRMA and presupposed that the Substance was fully consumed during vulcanisation. The Contested Decision draws different conclusions and thereby requires the lead registrant to update the exposure scenario on a '*realistic worst case basis'*.

108. The Appellant therefore argues that, since the conclusions of the exposure scenarios covering the uses that the Appellant makes of the Substance in the existing CSR and SDS were rejected in the Contested Decision, the lead registrant would have no alternative but to update its CSR and its SDS since the conclusions drawn in the Contested Decision may induce the introduction of risk management measures for the Substance. This, in turn, requires the Appellant, in its view, to provide the lead registrant with sufficient information to update the exposure scenario for the use of the Substance in tyres. The Appellant considers that, unless the Contested Decision is annulled, it would also have to prepare its own CSR because the Contested Decision concludes that the Substance was not fully consumed during vulcanisation whereas the Appellant holds an opposite view. Under Section 0.5 of Annex I, the Appellant would then be obliged to reflect on its difference of view in its CSR and, under Article 38, to report the information to the Agency.

109. The Appellant claims that its legal situation as a new registrant is also directly affected by the Contested Decision because it will need to update its registration dossier with the information submitted by the addressees of the Contested Decision and will have to bear part of the costs of generating the requested information. The Appellant argues that, having formalised its willingness to register the Substance at the time the Contested Decision was adopted, it will also have to submit an individual CSR in accordance with Article 10(b).

110. The Appellant contends that its legal situation as a SIEF participant is directly affected by the Contested Decision because, under the REACH Regulation, it must provide the addressees of the Contested Decision with the information required under Part III, Section c) and d) of the Contested Decision, which its addressees do not have. In particular, the Appellant argues that SIEF participants must, under Article 29, provide other SIEF participants with existing studies and react to their requests for information.

111. The Appellant further argues that it is a signatory of the SIEF agreement and consequently bound by it. According to the Appellant, that agreement provides, inter alia, that '*[t]he Appellant shall compensate with the payment of a "Joint Registration Compensation" which notably includes the expenses incurred for developing the Joint Registration Dossier*' and '*[i]n case new studies have to be purchased or performed after conclusion of this Agreement, the resulting cost will be equally divided between all SIEF participants who are required to incorporate the results of these new studies into their registration dossier.*' The Appellant argues that, as a potential registrant, it will be under an obligation to contribute to the costs triggered by the Contested Decision. The Appellant claims that its legal situation was directly affected because, even though it has not yet been required to share the costs involved as a result of the Contested Decision, these contractual obligations were certain and planned. The Appellant adds that this obligation is a direct consequence of the adoption of the Contested Decision.

112. The Appellant also submits that the admissibility criteria of direct and individual concern in Article 92(1) mirror the criteria included in the Treaty on the Functioning of the European Union (hereinafter the 'TFEU') at the time of the adoption of the REACH Regulation in December 2006 but that the Lisbon Treaty has since then provided the possibility for a natural or legal person to contest a regulatory act with no implementing measures provided that it demonstrates that it is directly concerned by such act. The Appellant argues that this possibility provides more flexible access to the EU courts as there is no longer a need to demonstrate individual concern.

113. Finally, the Appellant argues that it would be sound for the Board of Appeal to provide for more inclusive standing requirements for downstream users wishing to appeal a final substance evaluation decision affecting them, especially when such a downstream user is an identifiable data holder and when such a decision includes information requests concerning the use of that downstream user.

Findings of the Board of Appeal

114. Article 92(1) provides that '*[a]ny natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former*.' As the Contested Decision is not addressed to the Appellant the Board of Appeal will examine whether the Contested Decision is of direct and individual concern to the Appellant.

115. As a preliminary point, the Board of Appeal rejects the Appellant's argument that the Board of Appeal should give a 'flexible' or 'inclusive' interpretation of the admissibility requirements set out in Article 92(1). It must be pointed out, in this regard, that, whilst the Lisbon Treaty introduced the possibility for applicants to challenge regulatory acts which are of direct concern to them and do not entail implementing measures, it has not affected the definition of direct and individual concern. In any event, the Contested Decision is not a regulatory act but a decision addressed to registrants of the Substance.

116. When interpreting the concepts of direct and individual concern in Article 92(1), the Board of Appeal is guided by the case-law of the EU Courts on the fourth paragraph of Article 263 TFEU (see Case A-022-2013, *REACheck Solutions,* Decision of the Board of Appeal of 15 March 2016, paragraphs 69 and 83).

117. The Board of Appeal observes further that direct and individual concern are cumulative requirements and an appeal is inadmissible if an appellant fails to establish either of these requirements (see, by analogy, judgment of 3 October 2013, *Inuit Tapiirit Kanatami and Others* v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraph 76).

118. The Board of Appeal will first examine whether the Appellant meets the requirement of direct concern by analogy to the interpretation of the EU Courts.

119. In order to satisfy the requirement that a contested decision must be of direct concern to a person, two cumulative criteria must be met. First, a contested decision must directly affect the legal situation of an appellant and, second, it must leave no discretion to the authorities responsible for implementing it, such implementation being purely automatic and resulting from European Union law alone, without the application of other intermediate rules (see judgment of 27 February 2014, *Stichting Woonpunt and Others* v *Commission*, C-132/12 P, EU:C:2014:100, paragraph 68 and case-law cited).

120. The Board of Appeal notes, in relation to substance evaluation decisions, that Article 46(2) states '*[t]he registrant shall submit the information required to the Agency by the deadline set.*' The Board of Appeal therefore finds that the Contested Decision does not require any implementing measures. The second criterion of direct concern is therefore satisfied.

121. In order to satisfy the first criterion of the direct concern requirement, it must be established that a contested decision directly affects an appellant's legal, rather than factual, situation. The contested decision must produce legal effects with regard to an appellant. It is not sufficient that a contested decision exercises an influence over an appellant's substantive position or causes an appellant adverse economic consequences because they do not affect an appellant's legal situation, only its factual situation (see, to this effect and by analogy, order of 9 November 2015, *Biofa* v *Commission*, T-746/15, EU:T:2016:658, paragraphs 37 and 38). The Court of Justice has also consistently held that the direct effect on an applicant's legal situation cannot consist only of a competitive disadvantage (see for example judgment of 17 September 2015, *Confederazione Cooperative Italiane and Others* v *Anicav and Others*, C-455/13 P, EU:C:2015:616, paragraph 48 and 49 and the case-law cited).

122. The Appellant argues that it is directly concerned by the Contested Decision because of its status as a downstream user, SIEF Participant and signatory to the SIEF agreement, member of the S&T consortium and new registrant. The Board of Appeal will therefore examine, in turn, whether the first criterion of direct concern, namely that the Contested Decision must affect the Appellant's legal situation directly, is satisfied in any of these roles.

The Contested Decision's direct concern to the Appellant as a downstream user

123. The Appellant alleges that it is directly concerned by the Contested Decision because, given the need to generate new information, it may result in a price increase for the Substance or the registrants may stop manufacturing the Substance. Furthermore, as the Contested Decision raises concerns over the Appellant's use of the Substance, it may adversely impact the perception and 'marketability' of the Appellant's tyres.

124. The Board of Appeal finds, in this regard, that, although it cannot be excluded that the Contested Decision will have these effects, they are not sufficient to render the Appellant directly concerned because they do not affect its legal situation. They constitute economic consequences and consequently affect the Appellant's factual situation. In accordance with the case-law cited in paragraph 121 above, this is not sufficient to render the Appellant directly concerned. In addition, the Board of Appeal observes that these consequences do not stem directly from the Contested Decision as they depend on actions on the part of the addressees of the Contested Decision.

125. As regards the Appellant's arguments alleging that the Contested Decision may result in additional risk management measures, the Board of Appeal observes that the Appellant's arguments are based on the premise that the addressees of the Contested

Decision will be unable to provide the information necessary to dispel the concerns raised by the Contested Decision. The Board of Appeal considers this scenario hypothetical as there remains the possibility that the addressees of the Contested Decision will provide sufficient information to ensure that no additional regulatory risk management measures are needed. Furthermore, even if new risk management measures were required in the future, they would not render the Appellant directly concerned by the Contested Decision. Such risk management measures would not be a direct consequence of the Contested Decision, but of further action by the relevant authorities.

126. The Appellant also claims to be directly concerned by the Contested Decision because its addressees are required to update their CSR and SDS and the Appellant will have to provide them with the information they need for this purpose. Furthermore, the Appellant considers that, as the information the Appellant provides could contradict the premise in the Contested Decision that the Substance may still be present after vulcanisation, it would have to prepare its own CSR and, under Article 38, submit a downstream user report.

127. The Board of Appeal observes that the Appellant's arguments are based on the premise that the addressees of the Contested Decision will not be able to provide information proving the validity of the assumption that no trace of the Substance remains in tyres after vulcanisation and upon which the registrants based their CSR and SDS. Even though this assumption is called into question by the reasoning in the Contested Decision, the Board of Appeal observes that there is no reason to believe that the Agency and the German MSCA would reject reliable new information made available to them showing that the Substance is not present in tyres after vulcanisation. It follows that the scenario described by the Appellant in which it is required to perform its own CSR remains hypothetical. For this reason, it cannot be concluded that the Appellant will be required to compile its own CSR or submit a downstream user report to the Agency.

128. Regarding the Appellant's argument that it is directly concerned because it has an obligation, under Article 37(2), to provide the addressees of the Contested Decision with the information necessary to comply with that decision, the Board of Appeal has already found, at paragraph 80 above, that Article 37 does not impose any obligation to provide the information at issue. Article 37(2) provides a 'right' for a downstream user to make its use known to its supplier and, in making a use known, to provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance to prepare an exposure scenario. In any case, the alleged obligation to provide information is a direct consequence of Article 37(2) and does not result directly from the information request laid down in the Contested Decision.

129. Therefore, the Board of Appeal concludes that the Contested Decision does not directly affect the Appellant's legal situation in its role as a downstream user.

The Contested Decision's direct concern to the Appellant as a SIEF participant

130. The Board of Appeal observes that the Appellant makes two arguments as regards the Contested Decision's direct concern to the Appellant as a SIEF participant. It argues firstly that its SIEF participation means that its legal situation is directly affected by the obligation to share data with the other SIEF participants. It argues secondly that the contractual provisions of the SIEF agreement mean that its legal situation is directly affected by its obligation to share with the other SIEF participants the costs involved as a result of the Contested Decision.

131. The Board of Appeal will firstly consider whether the Appellant, as a SIEF participant, is directly concerned by the Contested Decision because its data-sharing obligations would require it to provide the addressees of the Contested Decision with the information requested therein.

132. It must be observed, in this regard, that Article 29(3) requires SIEF participants to '*provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies for the purposes of [registration] and arrange for such studies to be carried out*'.

133. The Appellant became a participant in the SIEF before the adoption of the Contested Decision. The Appellant may therefore be subject to certain obligations towards other SIEF participants insofar as the Contested Decision could lead to a '*request by other participants for information*' in accordance with Article 29(3).

134. However, it must be observed that, as is apparent from the wording of Article 29(3), any data-sharing obligations to which the Appellant may potentially be subject within the SIEF stem not from the Contested Decision itself, but from a request for further information by other SIEF participants. It follows that the Appellant cannot claim to be directly concerned by the Contested Decision *per se* on the ground of potential data-sharing obligations under Article 29.

135. Furthermore, it should be noted that the obligation, under Article 29, to which the Appellant may be subject is an obligation to '*react*' to a request for information. Although the Contested Decision may eventually give rise to such a request, this does not imply direct consequences on the legal situation of the Appellant as a result of the Contested Decision. In addition, information requests under Article 29, whilst they may imply economic consequences for the Appellant, do not have a direct effect on the legal situation of the Appellant (see paragraph 124 above).

136. The Board of Appeal therefore finds that the Appellant's potential data-sharing obligations as a SIEF participant under the REACH Regulation are not sufficient to establish that it is directly concerned by the Contested Decision.

137. The Board of Appeal will next examine whether the Appellant is directly concerned as a member of the S&T Consortium or by virtue of its potential cost sharing obligations as a party to the SIEF agreement.

138. As a member of the S&T Consortium, the Appellant is required to bear a share of '*the technical costs when updating the dossier (inclusion of new studies in IUCLID and review of IUCLID and CSR)*'.

139. The Board of Appeal notes that the Appellant signed the Declaration of Accession to the S&T Consortium on 28 August 2015, that is after the Contested Decision was adopted.

140. The Board of Appeal observes that the Court of Justice has held, as regards individual concern, that this admissibility requirement must be met at the time the contested measure was adopted (see judgment of 24 January 2017, *Beul* v *Parliament and Council*, C-53/16 P, EU:C:2017:66, paragraph 28). The Board of Appeal considers that the same principle has to be applied in relation to direct concern. Any contrary interpretation would infringe the requirements of legal certainty and the need to avoid all discrimination or arbitrary treatment in the administration of justice (see for example, by analogy, in relation to the time limits for bringing proceedings, judgment of 18 June 2015, *Ipatau* v *Council*, C-535/14 P, EU:C:2015:407, paragraph 14 and the case-law cited). Furthermore, the case-law also clearly demonstrates that it is the contested decision itself which must directly affect the legal situation of an appellant. It is therefore necessary to examine whether any possible change in the Appellant's legal situation is due to the contested decision or to any other reason.

141. It follows that as the Appellant only joined the S&T Consortium after the Contested Decision was adopted it cannot rely upon possible cost-sharing obligations resulting from its membership of the S&T Consortium to establish that it is directly concerned by the Contested Decision.

142. Title I of the SIEF agreement provides that the parties '*agree on the operating rules governing the exchanges of information between the SIEF potential registrants*'. Article

IX.8 of the agreement provides that '*[i]n case new studies have to be purchased or performed after the conclusion of the Agreement, the resulting cost will be equally divided between all SIEF participants who are required to incorporate the results of these new studies into their registration dossier*.'

143. The Board of Appeal notes that, on 19 October 2015, the Appellant received a notification from the Agency that its registration of the Substance, under Article 8(1), as the only representative for two non-EU legal entities, was successful.

144. The Board of Appeal observes that the Appellant's cost sharing obligations under the SIEF agreement were not triggered by the Contested Decision but rather by its registration of the Substance. This is because the SIEF agreement states that the Appellant is only required to share the costs of studies that will be included in its '*registration dossier'*. Therefore, without a registration dossier there would be no requirement to share costs. The Board of Appeal observes that, as set out in paragraph 140 above, the Appellant must show that it was directly concerned at the time the Contested Decision was adopted. The Board of Appeal therefore finds that the Appellant is not directly concerned by the Contested Decision because the Appellant's potential cost-sharing obligation as a party to the SIEF agreement came into effect only when it became a registrant of the Substance, which was after the Contested Decision was adopted.

145. In any event, the economic consequences for the Appellant of being required to share costs under the SIEF agreement are not capable of rendering the Appellant directly concerned by the Contested Decision. This is because, as noted in paragraph 124 above, any requirement to share costs only affects the Appellant's factual, rather than legal, situation.

146. The Board of Appeal finds therefore that the Contested Decision did not impose on the Appellant any additional legal obligations that it did not already have as a consequence of the SIEF agreement. Furthermore, the Board of Appeal finds that the Appellant is not directly concerned by the Contested Decision in its role as signatory to the S&T Consortium.

The Contested Decision's direct concern to the Appellant's as a new registrant of the Substance

147. Finally, the Board of Appeal will examine whether the Appellant is directly concerned by the Contested Decision as a new registrant of the Substance. The Appellant argues that, as a new registrant, it is directly affected by the Contested Decision because the Contested Decision requires it to update its registration dossier and to submit an individual CSR.

148. The Board of Appeal observes that, as set out in paragraph 23 above, the Appellant became a registrant of the Substance after the Contested Decision was adopted. Therefore, any obligation that the Appellant has to update its registration dossier and submit an individual CSR only arose after the adoption of the Contested Decision.

149. The Board of Appeal recalls that the Appellant must show that it is directly concerned at the time the Contested Decision was adopted (see paragraph 140 above). Therefore, the Board of Appeal finds that the Appellant, as a new registrant in this particular case, is not directly concerned by the Contested Decision.

Conclusion

150. For all the reasons set out above, the Board of Appeal finds that the Appellant has not established that it is directly concerned by the Contested Decision.

151. As the requirements of direct and individual concern are cumulative (see paragraph 117 above), there is no need to determine whether the Appellant is individually concerned by the Contested Decision.

152. There is also no need to examine the Agency's doubts as to whether this appeal was filed in time.

153. It follows that the appeal is inadmissible.

Refund of the appeal fee

154. In accordance with Article 10(3) of Commission Implementing Regulation (EU) 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), if the appeal is considered inadmissible by the Board of Appeal, the fee shall not be refunded.

155. As the appeal is dismissed as inadmissible, the appeal fee shall not be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. Dismisses the appeal as inadmissible.

2. Decides that the appeal fee shall not be refunded.

Sari HAUKKA
On behalf of Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal