EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

29 July 2015

(Notified substance – Statement of non-compliance (SONC) – Procedure under Article 51 of the REACH Regulation)

Case number	A-019-2013
Language of the case	English
Appellant	Solutia Europe sprl/bvba, Belgium
Representative	Claudio Mereu Field Fisher Waterhouse LLP, Belgium
Intervener	Federal Public Service (FPS) Health, Food Chain Safety and Environment, Belgium
Contested Decision	SEV-C-0000003764-69-01/F adopted by the European Chemicals Agency on 25 July 2013

THE BOARD OF APPEAL

composed of Mercedes ORTUÑO (Chairman), Andrew FASEY (Technically Qualified Member and Rapporteur) and Barry DOHERTY (Legally Qualified Member)

Registrar: Sari HAUKKA

gives the following

Decision

Summary of the facts

1. On 25 October 2013, the Appellant lodged the present appeal at the Registry of the Board of Appeal in which it requested the Board of Appeal to annul the Contested Decision and order the European Chemicals Agency (hereinafter the 'Agency') to pay the costs of the appeal proceedings.

Background to the dispute

2. The Appellant submitted a notification for the substance N-(1,1-dimethylethyl)bis(2-benzothiazolesulfen)amide ('TBSI'; hereinafter the 'Substance') to the Belgian competent authorities in accordance with the national legislation implementing Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

3. On 30 January 2008, the Belgian competent authorities requested further information from the Appellant in accordance with the national legislation implementing Directive 67/548/EEC (ref: MRB/CGP/CH/2008/1388; hereinafter the 'request of the Belgian competent authorities'). In that request the Appellant was asked to provide information on a toxicokinetic study (OECD 417), and an in-vitro mammalian cell genotoxicity test (chromosomal aberration test or mouse lymphoma assay).

4. Article 135(1) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless otherwise stated) provides that '*[t]he requests to notifiers to provide further information to the competent authority in accordance with Article 16(2) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 51 of [the REACH Regulation]'*.

5. On 29 June 2011, the Agency sent the Appellant a reminder regarding the request of the Belgian competent authorities. In this letter, the Agency stated that it expected the Appellant to provide the requested information without delay and invited the Appellant to inform the Agency, within 30 days, when the information would be available.

6. On 20 July 2011, the Appellant informed the Agency, inter alia, that it intended to submit an update of its registration dossier.

7. On 2 January 2012, the Appellant submitted a dossier update to the Agency. Specifically, for the in-vitro mammalian cell genotoxicity test requirement the Appellant submitted the requested information using a read across adaptation. For the toxicokinetic study requirement, the Appellant provided supportive information on the intrinsic properties and toxicological profile of the Substance.

8. On 25 July 2013, after consulting the Belgian competent authorities, the Agency sent the Contested Decision, entitled '*Statement of Non-Compliance following a Dossier Evaluation Decision Under Regulation (EC) No 1907/2006*' (hereinafter the 'SONC'), to the Belgium REACH Competent Authority. The SONC was notified at the same time to the Appellant, in its capacity as the registrant, via REACH-IT. In the SONC the Agency stated that the Appellant's registration dossier was non-compliant on the grounds that it did not contain the two studies required by the request of the Belgian competent authorities. In particular, the SONC stated that:

   '*…In conclusion, the dossier does not contain the information requested by the [request of the Belgian competent authorities]….*

On this basis [the Agency] states that:
- *The Registrant has not met the obligations following from the [request of the Belgian competent authorities];*
- *The registration dossier is not in compliance with Article 5…; and*
- *The Registrant is in breach of Article 41(4)….*

The non-compliance with the decision and the REACH Regulation may be subject to enforcement actions by the national authorities of the Member States as established in Article 126.

On this matter you are therefore asked to address the non-compliance in your own competence by means of enforcement.'

9. An attachment to the SONC set out the Agency's conclusions on the information submitted by the Appellant in its dossier update of 2 January 2012.

10. In relation to the in-vitro mammalian cell genotoxicity test the Agency stated in the attachment to the SONC that *'the request in the decision is not met.'* The Agency added that *'[the Agency] assessed the read across justification and concluded that the information provided is not meeting the REACH requirements.'* The Agency explained why '*the read across justification is not accepted by [the Agency]*' as follows:

'1. The read across is based on the expectation of ready hydrolysis of source substance and target substance to identical hydrolysis products. However, no data are presented that support this expectation.

2. The OECD SIDS report (2003) on the read across substance […] indicates a hydrolysis rate of the parent substance of 2 hours or longer at physiological pH, which indicates that exposure to the parent substance will be substantial. To note this report is only quoted by the registrant and was not added in attachment.

3. The difference in chemical structure between target and source may well go with differences in hydrolysis rate and, thereby, differences in exposure to the parent substances.

4. In view of the differences in chemical structure between target substance and source substance, different hydrolysis profiles are expected. There is no consideration what impact such differences have on the proposed read across.

5. In Annex XI, Section 1.5 […] it is stated "-adequate and reliable documentation of the applied method shall be provided". The documentation provided is not adequate. In particular, it is not adequately documented that due to hydrolysis the source and target substance will have identical effects in in-vitro mutagenicity studies.'

11. In relation to the toxicokinetic study, the Agency stated in the attachment to the SONC that the Appellant had provided *'…theoretical considerations without experimental evidence'*.

12. The attachment to the SONC ended with the following conclusion:

'As detailed above the request in the decision was not met. The Article 42(2) notification on information received and conclusions made will be on hold until all information has been received.'

13. On 18 February 2014, the Appellant updated its registration dossier with some of the information included in the request of the Belgian competent authorities.

Procedure before the Board of Appeal

14. On 25 October 2013, the Appellant lodged the present appeal at the Registry of the Board of Appeal.

15. On 23 December 2013, the Federal Public Service (FPS) Health, Food Chain Safety and Environment (hereinafter the 'Intervener') applied to intervene in the proceedings before the Board of Appeal supporting the remedy sought by the Agency. By Decision of 12 February 2014, the Board of Appeal, having heard the Parties, granted the application to intervene.

16. On 17 January 2014, the Agency submitted its Defence addressing the admissibility of the appeal and requesting the Board of Appeal to dismiss the appeal as inadmissible and *'order the Appellant to pay his costs'.*

17. On 20 January 2014, since a member of the Board of Appeal was precluded from participating in the proceedings, the Chairman, pursuant to the first subparagraph of Article 3(2) of 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'), designated an alternate member, Barry Doherty, to act in the present case as the legally qualified member of the Board of Appeal.

18. On 12 March 2014, the Appellant submitted its observations on the Defence and responded to certain questions from the Board of Appeal. On the same date, the Agency and the Intervener responded to certain questions of the Board of Appeal. The Intervener also provided its statement in intervention.

19. On 12 and 16 May 2014 respectively, the Appellant and the Agency lodged their observations on the submissions of the Intervener made to that point.

20. On 28 August 2014, the Appellant provided observations on the Agency's and Intervener's replies to the Board of Appeal's questions.

21. On 1 September 2014, following a request from the Board of Appeal, the Agency submitted a Defence on the substance of the case.

22. On 9 October 2014, following a request from the Board of Appeal, the Appellant and the Agency submitted copies of the information submitted by the Appellant to the Agency on 2 January 2012 in response to the request of the Belgian competent authorities.

23. On 10 October 2014, the Agency submitted a document to the Registry in which it questioned the Appellant's continued interest in pursuing the appeal due to the registration dossier updates submitted by the Appellant during the appeal proceedings. On 21 October 2014, the Agency also requested the opportunity to provide observations on the latest information submitted by the Appellant.

24. On 21 October 2014, the Agency responded to the Board of Appeal's request to comment on the accuracy of the information submitted by the other party on 9 October 2014.

25. On 3 and 4 November 2014 respectively, the Intervener and the Appellant provided their observations on the Agency's statement that the Appellant no longer had an interest in pursuing the appeal.

26. On 9 December 2014, the Agency provided observations on the Appellant's submission of 4 November 2014 and responded to certain questions from the Board of Appeal.

27. On 13 February 2015, the Parties responded to the Board of Appeal's invitation to comment on the possibility of a settlement being reached in the present appeal proceedings by confirming that they were unable to reach a settlement.

28. On 27 February 2015, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 13 March 2015, the Agency and the Appellant requested a hearing to be held. On 8 April 2015, the Intervener informed the Board of Appeal that it would not attend the oral hearing. In accordance with Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 19 May 2015. At the hearing, the Parties made oral presentations and also responded to questions from the Board of Appeal.

Reasons

29. In support of the form of order sought, the Appellant claims firstly that the SONC is unlawful as it was adopted in violation of the procedural requirements and safeguards set out in Article 51.

30. Secondly, the Appellant claims that by requesting the toxicokinetic study and the in-vitro mammalian cell genotoxicity test the Agency committed a manifest error of assessment and went beyond the limits of its discretion under Article 41.

31. Thirdly, the Appellant claims that the SONC infringes the principle of proportionality and was adopted prematurely.

32. The Board of Appeal will firstly examine the Agency's claim that the Appellant did not have an interest in pursuing the appeal as it had provided some of the information required by the request of the Belgian competent authorities.

Continued interest in pursuing the appeal

33. During the present proceedings, the Agency informed the Board of Appeal that the Appellant had updated its registration dossier on 18 February 2014, in other words whilst the appeal was pending, with certain of the information requested by the Belgian competent authorities. The Agency specified that, according to its discussions with the Belgian competent authorities, the Appellant had collaborated with the latter to provide a report of the results obtained from an in vitro mammalian cell mutation assay (OECD 476).

34. The Agency stated further that it was reported in the Appellant's dossier update of 18 February 2014 that information on the toxicokinetics of the Substance was in the process of being generated. According to the Agency, the Appellant's dossier update referred to the fact that the Appellant was conducting an in vitro test as a first step in a tiered approach which it had discussed with the Belgian competent authorities. The Agency stated that the Appellant added in the dossier update that the need for further (in vivo) testing would be determined on the basis of the results of that test.

35. The Agency claims that the opinion it set out in the SONC has become outdated and irrelevant because it no longer referred to the latest version of the Appellant's registration dossier. The Agency therefore questioned the Appellant's interest in pursuing the appeal as it had provided, or was in the process of doing so, the information set out in the request of the Belgian competent authorities. The Agency states that by fulfilling the request of the Belgian competent authorities the Appellant had de facto acknowledged the validity of the concerns set out in that request.

36. During the proceedings, the Appellant confirmed that in February 2014 it had provided the results of an in-vitro mutagenicity test (OECD 476) in a dossier update. The Appellant stated that it had not provided the in-vivo toxicokinetic test (OECD 417) but was in the process of obtaining data from a preliminary in-vitro study. The Appellant stated, however, that it still maintained that the requested toxicokinetics study (OECD 417) was not necessary. Furthermore, the Appellant maintains that its read across adaptation should have been accepted for the mutagenicity test but, '*to be on the safe side*' and without accepting the Agency's position, it provided the requested information.

37. The Appellant claims that it still has an interest in pursuing the appeal because the SONC has not been annulled and therefore continues to have legal effects. The Appellant claims that since the SONC states that the Appellant does not comply with Article 5 and is in breach of Article 41(4) the Appellant still faces the risk of sanctions and penalties from the national enforcement authorities. The Appellant states that, at a minimum, this risk remains for the period of time during which the SONC produced legal effects. According to the Appellant, '*[o]nly a ruling from the Board of Appeal annulling the Contested Decision would eliminate the Contested Decision from the legal order and its related consequences and legal effects…*'.

Findings of the Board of Appeal

38. The Board of Appeal notes that an appeal brought by a natural or legal person is admissible only in so far as that person has an interest in the annulment of the contested decision (see by analogy, for example, Joined Cases T-494/08 to T-500/08 and T-509/08, *Ryanair* v *Commission*, EU:T:2010:511, paragraph 41, and the Order in Case T-120/10, *ClientEarth and Others* v *Commission*, EU:T:2011:646, paragraph 46).

39. An appellant's interest in bringing proceedings must, having regard to the purpose of the action, exist at the stage of lodging the appeal, failing which the action will be inadmissible (see by analogy, for example, Joined Cases T-494/08 to T-500/08 and T -509/08, *Ryanair* v *Commission*, EU:T:2010:511, paragraph 42, and the Order in Case T-120/10, *ClientEarth and Others* v *Commission*, EU:T:2011:646, paragraph 47).

40. In addition, the interest in bringing proceedings must continue until the final decision. Failing this there will be no need to adjudicate, which presupposes that the appeal must be likely, if successful, to procure an advantage for the appellant (see by analogy, for example, Joined Cases T-494/08 to T-500/08 and T-509/08, *Ryanair* v *Commission*, EU:T:2010:511, paragraph 43, and the Order in Case T-120/10, *ClientEarth and Others* v *Commission*, EU:T:2011:646, paragraph 49).

41. If an appellant's interest in bringing proceedings disappears in the course of those proceedings a decision on the merits cannot bring it any benefit (see by analogy, for example, Joined Cases T-494/08 to T-500/08 and T-509/08, *Ryanair* v *Commission*, EU:T:2010:511, paragraph 44, and the Order in T-120/10, *ClientEarth and Others* v *Commission*, EU:T:2011:646, paragraph 50).

42. As a matter of principle, an appellant can still have a legal interest in bringing an appeal against a decision, even if the decision has been complied with (see by analogy Joined Cases 172/83 and 226/83, *Hoogovens Groep* v *Commission,* EU:C:1985:355, paragraph 19; Case T-22/97, *Kesko* v *Commission,* EU:T:1999:327, paragraph 59). This is subject to the proviso that the annulment of the decision must have legal consequences which would benefit the appellant (see, by analogy, Case T-306/11, *Schwenk Zement* v *Commission,* EU:T:2014:1233, paragraph 75 and Case T-46/92, *Scottish Football Association* v *Commission,* EU:T:1994:267, paragraph 14).

43. In this particular case, regarding the continued interest in seeking a Board of Appeal decision, the Appellant states that it is still at risk of enforcement action despite the fact that it has provided some of the information required. The Agency states that it is not involved in enforcement, which is a matter for the national authorities. As a result, there is no evidence before the Board of Appeal to disprove the Appellant's contention that it is still at risk of enforcement action.

44. Furthermore, during the present proceedings the Board of Appeal invited the Parties to comment on the possibility of a settlement in the dispute being reached, for example, by the Agency withdrawing the SONC while the Appellant simultaneously withdrew its appeal. The Agency informed the Board of Appeal that during the settlement discussions the Appellant requested assurance that the remaining information request would not be enforced for a period of one year, the time the Appellant anticipated it would need to provide the required toxicokinetics data which, according to the Agency, is required to bring the dossier into compliance. The Agency stated that since, pursuant to Articles 125 and 126, enforcement remains the exclusive competence of the Member States the Agency was not able to grant the assurances requested by the Appellant. According to the Agency, the Belgian competent authorities also stated that they would not be able to grant immunity from enforcement if a breach has been identified. The Belgian competent authorities, according to the Agency, highlighted that the Appellant's dossier had been non-compliant since 2008 and that immunity from enforcement would result in unequal treatment and be unfair towards registrants who comply with their regulatory obligations. The Agency stated therefore that there was nothing they could do to grant the Appellant immunity from enforcement action. The Agency underlines that the decision to enforce or not the request of the Belgian competent authorities remains exclusively in the hands of the Belgian authorities.

45. The Board of Appeal notes that the SONC has not been withdrawn by the Agency. The Agency maintains that the Appellant has not yet provided all the information required in the request of the Belgian competent authorities. As noted in the previous paragraph, neither the Agency nor the Belgian competent authorities can guarantee that the Appellant will not face enforcement action. Thus it cannot be ruled out that the Appellant may still face enforcement action, and that the SONC may be cited or used in such enforcement action. As a result, the Board of Appeal cannot exclude the possibility that the annulment of the SONC might be of benefit to the Appellant in preventing or defending any enforcement action taken by the Belgian competent authorities. The Appellant still therefore has an interest in pursuing the appeal (see by analogy, for example, Case T-306/11, *Schwenk Zement* v *Commission,* EU:T:2014:1233, paragraph 75 and Case T-46/92, *Scottish Football Association* v *Commission,* EU:T:1994:267, paragraph 14).

46. In addition, the Board of Appeal also considers that there is an interest in ensuring that the alleged unlawfulness, if it is found to exist by the Board of Appeal in the present proceedings, would not occur in the future in similar procedures. In particular, the Board of Appeal notes that in the present case the Appellant challenges not only the substance of the SONC but also the procedure employed by the Agency to adopt such acts. In particular, as is examined below, the Appellant alleges that the SONC was not adopted using the procedure foreseen in Articles 50 and 51 and as a result should be annulled. As a result, the Appellant's interest also extends to ensuring that the alleged unlawfulness would not recur in the future in a similar procedure to that at issue in the present proceedings, in particular by the issuing of a new SONC concerning the Substance (see by analogy, Case C-362/05 P, *Wunenburger*, EU:C:2007:322, paragraphs 41 to 61). The Appellant also has a legitimate interest in the Board of Appeal clarifying the legal conditions under which

the Agency has power to issue a SONC (see by analogy Case T-46/92, *Scottish Football Association* v *Commission,* EU:T:1994:267, paragraph 14).

47. In view of the above, the Board of Appeal considers that the Appellant still has an interest in pursuing the appeal and in a decision of the Board of Appeal regarding the Appellant's claim that the SONC should be annulled. The Agency's claim is therefore dismissed.

The Appellant's first plea alleging a violation of Article 51

48. The Appellant states that the Agency assessed the data submitted by the Appellant in its registration dossier and its subsequent update of 2 January 2012. The Appellant claims that, as a result, the SONC was a decision adopted by the Agency in the context of Article 41. The Appellant claims that this is supported by the fact that the SONC concludes that the Appellant's dossier does not comply with Article 41(4).

49. The Appellant also claims that, in accordance with Article 135, the SONC was adopted pursuant to Article 51 and according to Article 91 an appeal may be brought against such decisions. The Appellant adds that Article 51 in turn refers to decisions taken in the context of Article 41. The Appellant considers that the appeal is therefore subject to review by the Board of Appeal and is admissible.

50. The Appellant claims further that the SONC is unlawful as it was adopted in violation of the essential procedural requirements and safeguards set out in Articles 50 and 51.

51. The Appellant states in particular that, pursuant to Article 51, the Agency is required to notify its draft decision, together with the comments of the registrant, to the competent authorities of the Member States who may propose amendments. The Appellant adds that, ultimately, the final decision must be adopted by the Agency if there is a unanimous vote of the Member State Committee, failing which it is for the European Commission to adopt a decision. The Appellant states that in the present case the Agency adopted the SONC unilaterally, after consulting only the Belgian competent authorities, and without consulting the Member State Committee much less obtaining the unanimous approval of all Member States.

52. The Appellant claims that the request of the Belgian competent authorities must be regarded as a preparatory act which takes the form of a preliminary assessment prior to a compliance check under dossier evaluation. The Appellant adds that the SONC, and in particular the Agency's conclusions included as an attachment therein, constitutes the final determination of the compliance check in accordance with Articles 41 and 51. According to the Appellant, the data submitted by the Appellant in its dossier, and the read across adaptation and other arguments included therein, were only finally assessed and rejected by the Agency in the SONC. The Appellant claims that the Agency therefore took over substantially and procedurally the assessment started by the Belgian competent authorities and in doing so the Agency acted within the framework of Article 41. As a result, the Agency's final decision on the compliance check was adopted within the scope of Article 51.

53. The Appellant states that the procedure before the Belgian competent authorities, leading to the request of 30 January 2008, did not offer any procedural guarantees similar to those provided in Article 41. The Appellant claims in particular that exchanges between the Appellant and the Belgian competent authorities prior to the request of 30 January 2008 were only related to general, administrative matters and did not include any substantial discussions on the assessment of the Appellant's dossier.

54. Furthermore, the Appellant claims that the request of the Belgian competent authorities was not a challengeable act and cannot be considered as a decision on compliance check under dossier evaluation according to Article 135. Specifically the Appellant claims that the request of the Belgian competent authorities was only a proposal for further testing without any explanation or justification for the two additional studies and which only included a partial assessment as it indicated that the ecotoxicological data had not yet been assessed. Furthermore, it did not provide any deadline for providing the requested information. In addition, the Appellant claims that the Appellant did submit a read across adaptation and other arguments to the Belgian competent authorities explaining why the requested data was not necessary. However, no assessment of those submissions was made until the Agency took responsibility for evaluating the dossier. As a result the Appellant claims that the SONC cannot be considered to be a simple confirmation that the requested data was not submitted.

55. The Appellant claims that the SONC rejects the information provided by the Appellant and states that the registration dossier is not compliant with the REACH Regulation and, since it does not simply confirm the request of the Belgian competent authorities, it clearly has binding legal effects for the Appellant. The Appellant claims that this is supported by the fact that the SONC states that the Appellant is not compliant with Article 5 and is in breach of Article 41(4). The Appellant claims that by stating that the Appellant is not compliant with the REACH Regulation the SONC has a binding legal effect on the Appellant since it would no longer be able to manufacture or place the Substance on the market in the European Union.

56. The Agency, supported by the Intervener, claims that the appeal is inadmissible on the grounds that it concerns a SONC that does not produce binding legal effects that affect the interests of the Appellant by bringing about a distinct change in its legal position.

57. The Agency states that since the REACH Regulation does not explicitly describe the legal consequences for registrants that fail to comply with an evaluation decision imposing precise obligations, the Agency agreed with the Member State competent authorities to send SONCs to the relevant enforcement authorities. According to the Agency, a SONC is sent when the deadline in a decision has expired and, either no information has been submitted by the registrant or the Agency's expert opinion is that the information submitted by the registrant does not satisfy the request made in the decision. The Agency claims that in this respect it is fulfilling the requirements of Article 77(2)(h) according to which the Agency is obliged to provide '*technical and scientific guidance on the operation of [the REACH] Regulation for Member States competent authorities…*'.

58. The Agency states that, pursuant to Article 126, the national enforcement authorities have the exclusive competence in addressing infringements of the REACH Regulation. The Agency states that once a SONC has been issued the Agency has no legal competence to ensure that the registrant meets the precise requirements imposed by the initial decision. The Agency adds that it is entirely within the discretion of the Belgian enforcement authorities to decide whether to rely on the Agency's expert opinion and enforce their initial decision or to make a new assessment of the facts and subsequently choose whether to take enforcement action or not. According to the Agency, the Belgian enforcement authorities are in no way bound by the SONC. The Agency adds that there is no general understanding between the Agency and the Member State competent authorities that a SONC obliges the relevant enforcement authorities to take enforcement action accordingly.

59. The Agency claims that a SONC is merely a non-binding communication to the Member State enforcement authorities consisting of the Agency's analysis of the information in a registrant's dossier and its views as to whether the information provided satisfies the initial decision. The Agency claims that, as a result, a SONC does not create any new obligations for a registrant. According to the Agency, in this case, the legal position of the Appellant established in the request of the Belgian competent authorities is exactly the same following the issuance of the SONC.

60. The Agency claims that the intention of the legislator was to hold registrants accountable in order to ensure that the information required by the REACH Regulation is rapidly available and that the efforts of the authorities can be focused on the assessment of substances of major concern. The Agency claims that it would run counter to the objectives and purpose of the REACH Regulation, which aims to ensure a more efficient and coercive regulatory framework for chemicals in the European Union, if the authorities would have to issue new decisions instead of ensuring the effective enforcement of information requirements already explicitly requested. The Agency states that a system whereby the information communicated in a SONC would have to be adopted using the onerous decision-making procedure set out in Articles 50 and 51 would lead to paralysis of the enforcement of Agency decisions and create an endless loop of new decisions based on every dossier update addressing the requested information. The Agency claims that the intention of the legislator in adopting the REACH Regulation was to avoid this deficiency.

61. According to the Agency, pursuant to Article 42, the follow-up to dossier evaluation '*…may result in the following principle scenarios:*

- *The information received corresponds to the information requested in the decision and it fulfils the information requirement set out in the REACH Regulation. In that case the follow-up process shall be completed in accordance with Article 42(2).*
- *The information requested in the decision was not submitted, but the adaptation provided instead fulfils the information requirement concerned by the decision. In that case the follow-up process shall be completed in accordance with Article 42(2).*
- *The information received corresponds to the information requested in the decision, but it is not sufficient to fulfil the relevant information requirement(s). In that case the follow-up process is not completed and [the Agency] shall draft any appropriate evaluation decision requesting the necessary information, in accordance with Article 42(1).*
- *The information requested in the decision has been received or the information received does not correspond to the requested information in the decision and no adaptation was submitted. In that case the follow-up process cannot be completed and the competent Member State shall take any measure to ensure that the decision is implemented, in accordance with Article 126.*
- *An adaptation was submitted in place of the information requested but this adaptation does not fulfil the information requirement concerned by the decision. In that case the follow-up process cannot be completed and the competent Member State shall take any measure to ensure that the decision is implemented, in accordance with Article 126*'.

62. With regards to the statement in the SONC that '*the registration dossier is not in compliance with Article 5…*' the Agency states that even if the Belgian competent authorities decided to take enforcement action against the Appellant this would not have the effect of withdrawing or altering the status of the registration.

63. The Intervener claims that legal redress was available to the Appellant against the request of the Belgian competent authorities as it was an administrative act of a minister appealable before the competent Belgian court, the Council of State (*Conseil d'État/Raad van State)*.

64. The Intervener claims that the SONC has no specific legal basis and creates no legal effects on national competent authorities, citizens or companies. According to the Intervener, the SONC is only a way for the Agency to communicate with the national competent authorities. The Intervener claims further that enforcement action may be taken by a Member State regarding information missing from a registration dossier even before the Agency has issued a SONC.

Findings of the Board of Appeal

65. The Board of Appeal observes that it is undisputed between the Parties that the Substance is a notified substance within the meaning of point 21 of Article 3. The Board of Appeal also observes that, pursuant to Article 24(1), notified substances are to be regarded as registered for the purposes of the REACH Regulation and the Agency was obliged to assign the Appellant a registration number for the Substance by 1 December 2008, as happened in the present case.

66. As confirmed by the Intervener during the present proceedings, the Board of Appeal considers that the request of the Belgian competent authorities was adopted on the basis of the national law implementing Article 16(2) of Directive 67/548/EEC.

67. The Board of Appeal observes further that, pursuant to Article 135(1), '*[t]he requests to notifiers to provide further information to the competent authority in accordance with Article 16(2) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 51….*' Pursuant to Article 141(3), Article 135 has been applicable since 1 August 2008.

68. In view of the above, the Board of Appeal considers that the request of the Belgian competent authorities should be considered as a request to a notifier within the meaning of Article 135(1). As a result, pursuant to Article 135(1), the request of the Belgian competent authorities must be *'considered as'* an Agency decision *'adopted in accordance with Article 51'*. Article 51 states that '*[t]he Agency shall notify its draft decision in accordance with Articles 40 or 41…*'. The Board of Appeal finds that the request of the Belgian competent authorities can only be relevant to a compliance check pursuant to Article 41 and not to a testing proposal pursuant to Article 40. The Board of Appeal considers therefore that, in effect, the request of the Belgian competent authorities is equivalent to an Agency compliance check decision adopted pursuant to Article 41. This conclusion is further supported, for example, by the fact that the SONC itself refers to a breach of Article 41(4).

69. The Board of Appeal considers that this conclusion is not affected by the Appellant's arguments that the request of the Belgian competent authorities was not a challengeable act and cannot be considered as a final decision on compliance check under dossier evaluation pursuant to Article 135. In this respect the wording of Article 135(1) itself refers specifically to *'requests to notifiers'.* It is also clear that the Belgian competent authorities believed Article 135 applied and the Agency stated during the proceedings that it considered the request of the Belgian competent authorities to be subject to Article 135. In addition the SONC states that '*Article 135(1)…provides that these decisions are considered dossier evaluation decisions by the [Agency]*.'

70. For the purposes of the Appellant's first plea, the question for the Board of Appeal to consider therefore is whether, in examining the information submitted by the Appellant in response to the request of the Belgian competent authorities, namely the information submitted in the dossier update of 2 January 2012, the Agency was obliged to adopt a decision in accordance with Article 41 which refers to the procedures set out in Articles 50 and 51.

71. The Board of Appeal observes that the procedure for examining information submitted by a registrant following a compliance check decision adopted under Article 41 is set out in Article 42 which is entitled '*[c]heck of information submitted and follow-up to dossier evaluation*'. According to Article 42(1) '*[t]he Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary*'. Article 41(3) states that decisions '*…shall be taken in accordance with the procedure laid down in Articles 50 and 51*'.

72. The Board of Appeal finds that the Agency examined the information provided by the Appellant as a follow-up action consequent to the request of the Belgian competent authorities. In particular, the attachment to the SONC, entitled '*[a]ssessment of whether the request in the final decision is met*', consists of a detailed assessment of the proposed read across adaptation and other arguments provided by the Appellant in its dossier update of 2 January 2012. The Board of Appeal therefore considers that the Agency's assessment of the Appellant's dossier update of 2 January 2012, submitted in consequence of the request of the Belgian competent authorities which is equivalent to a decision taken under Article 41, must fall within Article 42(1), and not Article 41 as claimed by the Appellant.

73. The Board of Appeal will next examine whether in the present case, pursuant to Article 42(1), it was necessary for the Agency to draft a decision in accordance with Article 41 and in turn go through the decision-making procedure foreseen in Articles 50 and 51.

74. The Board of Appeal accepts that Article 42(1), in providing that the Agency is required to draft a decision in accordance with the procedure in Article 41 '*if necessary'*, grants the Agency a certain amount of discretion as to when it is required to adopt a new decision.

75. In this regard, the Agency stated during the present proceedings that '*Article 42(1) allows [the Agency] to consider issuing further decisions based on the information submitted by a Registrant in response to an [Agency] decision. This implies that the decision initially adopted was correctly implemented by the registrant, but that the information submitted was nonetheless still insufficient to comply with the information requirement'*. The Agency considers that a new decision '*… is necessary only when the assessment of the information submitted in consequence of a previous compliance check decision results in the need to require other information than the information initially requested.'* The Agency claims that '*[i]n the present case, there was no need to draft a new decision, since the information provided by the Appellant did not give rise to a new concern*'. According to the Agency, the information provided by the Appellant was not sufficient to address the request of the Belgian competent authorities. The Agency claims that as a result it was not necessary to draft a new decision and go through the decision-making process set out in Articles 50 and 51.

76. The Agency also claimed during the present proceedings that the SONC is not a decision open to appeal since it does not modify the Appellant's obligations. According to the Agency, the obligations placed on the Appellant remained the same at the time the SONC was issued as those set out in the request of the Belgian competent authorities. The Agency argues that Article 42(1) cannot require a new decision which would simply repeat an existing obligation.

77. The Board of Appeal accepts that the Agency would not be required to draft a new decision pursuant to Article 42(1), following the procedures foreseen in Articles 50 and 51, where that decision would merely confirm the previous decision. In this regard, a measure is regarded as merely confirmatory of a previous decision if it contains no new factor as compared with the previous measure and was not preceded by a re-examination of the circumstances of the person to whom that measure was addressed (see Case T-308/02, *SGL Carbon* v *Commission,* EU:T:2004:119*,* paragraph 51, and Case T-186/98, *Inpesca*, EU:T:2001:42, paragraph 44). However, the confirmatory or other nature of a measure cannot be determined solely with reference to its content as compared with that of the previous decision which it confirms. The nature of the contested measure must also be appraised in the light of the nature of the request to which it constitutes a reply (see Case T-308/02, *SGL Carbon* v *Commission,* EU:T:2004:119*,* paragraph 52, and Case T-186/98, *Inpesca*, EU:T:2001:42, paragraph 45).

78. In particular, if the measure constitutes the reply to a request in which substantial new facts are relied on, and whereby the administration is requested to reconsider its previous decision, that measure cannot be regarded as merely confirmatory in nature, since it constitutes a decision taken on the basis of those facts and thus contains a new factor as compared with the previous decision (see Case T-308/02, *SGL Carbon* v *Commission,* EU:T:2004:119*,* paragraph 53, and Case T-186/98, *Inpesca*, EU:T:2001:42, paragraph 46).

79. In the case-law of the European Union courts, facts are considered new if neither the applicant nor the administration could have had prior knowledge of them (see Case T-308/02, *SGL Carbon* v *Commission,* EU:T:2004:119*,* paragraph 57, and Case T-186/98, *Inpesca*, EU:T:2001:42, paragraph 50). Information is considered substantial if it is capable of substantially altering the applicant's legal situation from that which prevailed when the earlier decision was adopted (see Case T-308/02, *SGL Carbon* v *Commission,* EU:T:2004:119*,* paragraph 58, and Case T-186/98, *Inpesca*, EU:T:2001:42, paragraph 51).

80. Whilst the Board of Appeal acknowledges that a read across adaptation, for example, may not strictly speaking be a new fact and that the Agency's assessment of a registration dossier update is not strictly speaking a '*reply to a request*', the Board of Appeal considers that the approach taken by the European Union Courts as outlined above should apply by analogy in this particular case. The Board of Appeal will therefore examine whether in the present case the information submitted by the Appellant on 2 January 2012 in response to the request of the Belgian competent authorities should be considered to be substantial new information.

81. In the present case, the Board of Appeal finds that the Agency carried out a scientific assessment of the new material provided on 2 January 2012 which is set out in a five page attachment to the SONC. As regards the request for an in-vitro mammalian cell genotoxicity test, the Agency assessed and subsequently concluded that the read across adaptation put forward by the Appellant should be rejected (see paragraph 10 above). In other words, the information submitted by the Appellant was such that a scientific assessment was required in order to conclude on whether the information requirements had been met.

82. The Board of Appeal also notes that the shortcomings identified in the request of the Belgian competent authorities were with regard to the notification requirements for new substances pursuant to Directive 67/548/EEC. At the time of the notification of the Substance, that Directive contained no equivalent to Article 13 of the REACH Regulation that requires registrants to provide information on intrinsic properties of substances through means other than vertebrate testing whenever possible, for example through the use of read across. In this respect, the Board of Appeal observes

that Article 1 of Directive 2006/121/EC of the European Parliament and of the Council amending Directive 67/548/EEC in order to adapt it to the REACH Regulation (OJ L 396, 30.12.2006, p. 850) states that Article 3 of Directive 67/548/EEC shall be replaced by: '*[t]ests on substances carried out within the framework of this Directive shall be conducted according to the requirements of Article 13 [of the REACH Regulation]*'. The Appellant was therefore compelled to submit information adapting the requirements set out in the request of the Belgian competent authorities if it considered that the adaptation possibilities in Annex XI applied.

83. Furthermore, and without taking a position on the Agency's conclusions regarding the read across adaptation of the testing requirement for an in-vitro mammalian cell genotoxicity test, the Board of Appeal notes that the proposed adaptation included a large number of test results for the endpoint from both the target and the source substance and provided a justification for the read across from the source to the target substance. Whilst accepting that the test results are of varying degrees of reliability, and acknowledging the complexity associated with justifying a read across adaptation, the Board of Appeal concludes that the Appellant had made a bona fide adaptation proposal, pursuant to Article 13 and Annex XI, and that this therefore required a scientific assessment.

84. In light of the above, the Board of Appeal concludes that the read across adaptation submitted by the Appellant in its registration update of 2 January 2012 must be considered to be substantial new information.

85. As a result, in the present case the SONC did not simply confirm the earlier request of the Belgian competent authorities. The Agency's scientific assessment of the Appellant's dossier update of 2 January 2012 resulted in a fresh decision (see by analogy for example, T-308/02, *SGL Carbon* v *Commission,* EU:T:2004:119*,* paragraphs 51 to 55 and Case T-186/98, *Inpesca*, EU:T:2001:42, paragraphs 44 to 55). As stated in paragraphs 81 to 84 above, the Board of Appeal considers that the Appellant had provided substantial new information which required a detailed scientific assessment by the Agency using the scientific expertise available to it.

86. The Board of Appeal finds therefore that the Agency was not merely re-assessing a situation considered by the Belgian authorities in 2008, but examining substantial new information provided in 2012. The Board of Appeal observes that this would not be the case for example if the Appellant had provided no, or minimal, new information which required little or no scientific assessment and the Agency was readily able to conclude that it was not necessary to re-consider the original decision.

87. Additionally, the Board of Appeal finds that the Appellant did not have the opportunity to comment on the Agency's conclusions contained in the SONC dismissing the adaptation of the information requirement for an in-vitro mammalian cell genotoxicity test by use of a read across and arguments it had submitted regarding the request for a toxicokinetic study in its dossier update of 2 January 2012. Prior to the present proceedings, the Appellant has not had the opportunity to express its views on those findings.

88. In accordance with settled case-law of the European Union Courts, observance of the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question (see Case C-32/95 P *Commission* v *Lisrestal and Others*, EU:C:1996:402, paragraph 21 and Article 41(2) of the Charter of Fundamental Rights of the European Union (OJ 2010 C 83, 30.3.2010, p. 389). That principle requires that the addressee of a decision which significantly affects its interests should be given the opportunity to effectively make known its views on the correctness and relevance of the facts, objections and circumstances put forward by

the institution (see for example Case T-314/01, *Avebe* v *Commission*, EU:T:2006:266, paragraph 49 and the case-law cited therein).

89. The Board of Appeal also considers that, in the present case where the request of the Belgian competent authorities required testing on vertebrate animals, following the procedure set out in Articles 50 and 51 might have helped to ensure that testing on vertebrate animals is undertaken only as a last resort pursuant to Article 25(1). In this respect, as stated above in paragraph 82, the Board of Appeal observes that Article 1 of Directive 2006/121/EC states that Article 3 of Directive 67/548/EEC shall be replaced by: '*[t]ests on substances carried out within the framework of this Directive shall be conducted according to the requirements of Article 13 [of the REACH Regulation]*'. In other words, alternative methods need to be used wherever possible to satisfy information requirements. In this particular case, as reflected in the five page attachment to the SONC, the Agency did make an assessment of the information submitted by the Appellant pursuant to Article 13 as required by Article 41(1)(b) but this assessment and its conclusions were not subjected to the procedural guarantees established in Articles 50 and 51.

90. Finally, and whilst not decisive, from the evidence submitted during these proceedings the Board of Appeal notes that the Appellant did not have a formal opportunity to comment on the request of the Belgian competent authorities during its preparation in a way comparable with the procedural guarantees given to registrants under Articles 50 and 51. The Board of Appeal asked the Intervener what procedures were followed before the Belgian authorities issued their request on 30 January 2008. The Intervener replied that the request of 30 January 2008 followed on from the fact that the Appellant notified the Belgian competent authorities that it would be placing more than 10 tonnes of the Substance on the market annually. The reply did not refer to any possibility for the Appellant to comment before the request of the Belgian competent authorities was sent. The Intervener states that the Appellant could have challenged this request before the Council of State. The Appellant disagrees. Both the Intervener and the Appellant invoke rules of Belgian law to support their claims. The Board of Appeal is not required to resolve this disagreement, but notes that no remedy other than a court challenge has been identified.

91. In view of the above, the Board of Appeal finds that the Agency should have adopted a decision pursuant to Article 42(1), and the procedure laid down in Articles 50 and 51, following its assessment of the substantial new information provided by the Appellant on 2 January 2012. The information supplied by the Appellant was '*information submitted in consequence of a decision taken under Articles 40 or 41'* since under Article 135, the request of the Belgian competent authorities is considered equivalent to a decision adopted under Article 41. Thus, the Agency was under a duty to examine the information and '*draft any appropriate decisions'.* Article 42(1) specifies that such decisions are to be drafted in accordance with Articles 40 or 41, which refer to the procedures in Articles 50 and 51. The Agency did not therefore fulfil the obligations imposed by Article 42(1). It examined the new information and reached the conclusion that the Appellant had not met its obligations. However, this conclusion was not communicated in a decision adopted in accordance with the procedures in Articles 50 and 51. Instead, the Agency adopted a document not defined in the REACH Regulation, the SONC, depriving the Appellant of the procedural guarantees defined in Articles 50 and 51. Thus, the Board of Appeal finds that the Agency breached Article 42(1). The SONC is therefore annulled and remitted to the Agency for further action.

92. Since the Board of Appeal has decided in favour of the Appellant on the first plea it is not necessary to examine the Appellant's remaining pleas.

Admissibility of an appeal against a SONC

93. In the light of the above, the Board of Appeal will finally address the inadmissibility arguments raised by the Agency regarding an appeal against a SONC.

94. The Agency firstly argues that the SONC does not modify the Appellant's legal obligations. According to the Agency, the Appellant's obligations were defined by the request of the Belgian competent authorities and the SONC did not modify those obligations since it did not require the Appellant to provide anything not already requested by the Belgian authorities. Secondly, the Agency denies that the SONC causes the Belgian authorities to take enforcement actions against the Appellant. Supported by the Intervener, the Agency argues that enforcement is purely a matter for the Member States and that the SONC cannot compel enforcement actions.

95. The Board of Appeal rejects the Agency's first argument. As explained in paragraphs 65 to 91 above, contrary to the Agency's contentions, the SONC included a new decision which modified the Appellant's legal situation. The Agency assessed the substantial new information supplied by the Appellant on 2 January 2012 and concluded that it was not sufficient to comply with the Appellant's obligations. For the reasons given above, this assessment resulted in a separate and new decision and not merely a confirmation of an existing decision. Furthermore, the SONC states that the procedure *'will be on hold until all information has been received.'* The Agency therefore did not adopt a new decision under Article 42(1) which would have given the Appellant certain procedural rights.

96. As the Board of Appeal has found above, the Agency's assessment of, and conclusions on, the Appellant's dossier update, submitted to meet the request of the Belgian competent authorities, should have led to a decision adopted under Article 42(1). This provision refers to the procedures established in Article 41, which in turn refers to the procedures laid down in Articles 50 and 51. A decision dismissing the Appellant's adaptation proposal and other arguments should therefore have been adopted following the procedures set out in Articles 50 and 51. By adopting a SONC containing a conclusion following the scientific assessment of substantial new information the Agency therefore breached Article 42(1) and Articles 50 and 51.

97. Under Article 91, the Board of Appeal has jurisdiction over decisions taken pursuant to Article 51. By referring to Article 51, the legislator clearly intended to cover decisions adopted under Articles 40, 41 and 42(1), whose procedural rules are to be found in Article 51. For the reasons given above, this SONC was an act having legal effect whose content falls squarely within Article 42(1) and Article 41. The system of remedies in the REACH Regulation would be circumvented if the Agency could adopt such acts but avoid the jurisdiction of the Board of Appeal.

98. The appeal is therefore admissible, without it being necessary to decide on the Agency's second argument on enforcement.

Other issues under examination

Refund of the appeal fee

99. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.

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

Claim for reimbursement of costs

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

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

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

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the statement of non-compliance of 25 July 2013 with the reference number SEV-C-0000003764-69-01/F.**

2. **Remits the case to the competent body of the Agency for re-evaluation.**

3. **Orders the refund of the appeal fee.**

4. **Rejects the claim for the reimbursement of costs incurred by the Appellant in the appeal proceedings.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal