

-ENGLISH VERSION-

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

# 15 March 2016

(Registration – Individual submission of a registration dossier – Complaint of a lead registrant for a joint submission – Admissibility – Direct and individual concern – Completeness check – Principle of 'one substance, one registration')

- Language German of the case
- Appellant REACheck Solutions GmbH, Germany
- RepresentativeAndreas KrellmannRechtsanwälte Singelmann & Bach
- Intervener Nikimol OOD, Bulgaria
- Contested SUB-D-2114256759-32-01/F of 19 July 2013 finding a registration for the substance charcoal to be complete and assigning a registration number, adopted by the European Chemicals Agency pursuant to Article 20 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')

# THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

## Decision

### Summary of the facts

1. On 12 December 2013, the Appellant, who is the lead registrant for the joint submission for charcoal (hereinafter the 'Substance'), lodged the present appeal at the Registry of the Board of Appeal. The Appellant requests the Board of Appeal to annul the Contested Decision finding the registration dossier submitted individually by Nikimol OOD (hereinafter the 'Intervener') to be complete and assigning a registration number to the Intervener for its registration of the Substance.

## Background to the dispute

- 2. On 25 November 2010, the Appellant submitted to the Agency a registration dossier for the Substance as the lead registrant for the joint submission. The dossier included information on studies in accordance with Articles 10 and 11(1) of the REACH Regulation (all references to Recitals and Articles hereinafter concern the REACH Regulation unless stated otherwise). The completeness of the registration was confirmed by the Agency, which assigned a registration number to the Appellant.
- 3. On 13 March 2013, the Appellant wrote a letter to the Agency, complaining that several individual submissions had been made to the Agency for the registration of the Substance outside the joint submission. The Appellant stated that it had made unsuccessful attempts to contact the concerned companies. According to the Appellant, some of the companies that had submitted individual registration dossiers had used information provided in its lead registration dossier. The Appellant also stated that some of this information, including study results, was 'sponsored' by the Appellant and the other joint registrants for the creation of their individual dossiers and the joint submission. The Appellant further contended that some individual registration dossiers were devoid of any real content. It requested the Agency to revoke the registration numbers assigned to the individual registrants.
- 4. On 10 April 2013, the Agency replied to the Appellant's letter. The Agency indicated that the completeness check performed in accordance with Article 20 does not include a check of whether a registrant has permission to use the data included in its registration dossier. The individually submitted registration dossiers referred to by the Appellant were considered complete and there was no legal basis for the Agency to revoke the registration numbers as requested by the Appellant. The Agency offered to contact the companies referred to by the Appellant and inform them about the Appellant's letter. At the same time the Agency stated that it 'does not have any obligation or competence to interfere or act as an arbitrator in disputes relating to potential infringements of intellectual property rights between data owners and companies using this data for fulfilment of their duties.' The Agency further indicated that the Appellant 'may, however also consider to bring actions for breach of [its] copyright laws [sic] before national courts, in case the registrants have used the data without prior agreement from the data owner'.
- 5. On 12 June 2013, the Intervener submitted to the Agency via REACH-IT an inquiry regarding the Substance pursuant to Article 26(1). The Intervener's inquiry indicated that it concerned a '*non-phase-in substance*' and did not include any specific requests for information.

- On 8 July 2013, the Agency sent a standardised communication to the Intervener 6. stating that the Agency had conducted its assessment of the inquiry in accordance with Article 26. The Agency verified the substance identity and provided identifiers for the Substance, including the EC number and the assigned inquiry number. The Agency indicated that this information needed to be included in the Intervener's registration dossier. The communication also informed the Intervener that the names and contact details of previous and potential registrants of the Substance were available via the 'co-Registrants page' in REACH-IT. The Agency informed the Intervener that any previous or potential registrants would be notified of the inquiry in accordance with Article 26(3). The Agency further explained that '[p]ursuant to Articles 11 and 19 of the REACH Regulation, only one joint registration shall be submitted for this substance. Therefore all registrants of the same substance share a common duty to submit a joint registration dossier. If no registration for this substance has been submitted yet by any registrant, all potential registrants must agree on a registrant, who shall first submit the information specified in Article 11(1)[second subparagraph] of the REACH Regulation on behalf of the others (the lead registrant). Each registrant shall subsequently submit the information specified in Article 11(1)[third subparagraph] of the REACH Regulation. If a registration for the same substance has already been submitted by one or more other registrants, you are required to form a joint submission with them. Please note that failure to comply with your joint submission obligation will amount to a breach of the REACH Regulation, and you may be subject to further legal consequences as provided for in applicable national laws." The Agency also stated that '[u]nder Article 27 of the REACH Regulation, you are obliged to request information involving tests on vertebrate animals, required under Article 10(a)(vi) and (vii) of the REACH Regulation, from the previous registrants of the same substance. You may request information not involving tests on vertebrate animals. You shall make every effort to reach a fair, transparent and nondiscriminatory agreement on the sharing of existing information and the associated costs with the previous registrants."
- 7. Also on 8 July 2013, the Agency sent a message to the Appellant informing it of the Intervener's inquiry. The Agency's message included a link to the 'co-registrants page' in REACH-IT where 'contact details of the party that submitted the inquiry/requested additional information as well as the list of the information they requested' could be found.
- 8. On 10 July 2013, the Appellant sent an email to the Intervener inquiring whether the Intervener intended to register the Substance and what data it needed for the registration, adding that the Appellant could provide the necessary vertebrate animal studies immediately. The Appellant further stated that '[*i*]*f you are also interested in joint submission (including all additional robust studies) we can send you detailed information about the process and letter of access'.* No evidence has been submitted in these proceedings of any reply from the Intervener to the email sent by the Appellant or of any specific requests for information addressed by the Intervener to the Appellant or a third party.
- 9. On 16 July 2013, the Intervener submitted to the Agency, via REACH-IT, a registration dossier for the Substance for the tonnage band 100 to 1000 tonnes per year. On 19 July 2013, the Agency adopted the Contested Decision, finding the registration to be complete and assigning a registration number. The Intervener was listed on the Agency's dissemination website as a registrant of the Substance on 17 October 2013.

### Procedure before the Board of Appeal

- 10. On 12 December 2013, the Appellant lodged the present appeal at the Registry of the Board of Appeal. The appeal was lodged in German, which is therefore the language of the case.
- 11. On 21 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.
- 12. On 17 February 2014, the Agency submitted as its Defence observations on the admissibility of the appeal, requesting the Board of Appeal to dismiss the appeal as inadmissible.
- 13. On 21 February 2014, the Intervener submitted an application to intervene in the proceedings before the Board of Appeal, opposing the remedy sought by the Appellant.
- 14. On 25 February 2014, the Registrar of the Board of Appeal sent to the Intervener a request for regularisation of its application to intervene. The Intervener responded on 11 March 2014, submitting information and documents pertaining to the application to intervene.
- 15. On 23 April 2014, having heard the Parties' observations on the application to intervene, the Board of Appeal granted the Intervener's application to intervene in accordance with Article 8 of the Rules of Procedure. On the same date the Board of Appeal's intervention decision was notified to the Intervener, together with the copies of the procedural documents submitted by the Parties thus far in the proceedings. The Intervener was invited to lodge observations on those procedural documents.
- 16. On 7 March 2014, the Board of Appeal invited the Agency to respond to a number of questions concerning the admissibility of the appeal and the Contested Decision. In its submission of 7 April 2014, the Agency responded to the questions and requested the Board of Appeal to indicate whether it intended to dismiss the appeal as inadmissible so as to grant the Agency 'the opportunity to take position on the grounds in an exchange of written pleadings on the complete appeal'.
- 17. On 19 May 2014, the Appellant submitted observations on the Agency's Defence and on the Agency's replies to the questions of the Board of Appeal.
- 18. By letter dated 26 May 2014, the Intervener declined to submit observations, indicating that it had no information to add to the proceedings beyond that submitted in its application to intervene.
- 19. On 6 June 2014, the Parties and the Intervener were informed that the Board of Appeal had decided to reserve its final considerations on the admissibility of the appeal for the final decision and invited the Agency to provide observations on the substance of the case.
- 20. On 6 August 2014, the Agency submitted its observations on the substance of the case, on which the Appellant and the Intervener were invited to submit observations.

- 21. On 12 September 2014, the Appellant submitted its observations on the Agency's observations on the substance of the case, which were notified to the Agency and the Intervener. The Intervener did not submit any observations.
- 22. On 31 October 2014, the Board of Appeal invited the Agency to submit observations on the Appellant's observations and to respond to certain questions. The Intervener was informed of this request on the same day. On 1 December 2014, the Agency submitted its reply to the questions of the Board of Appeal. On the same date, the Agency informed the Board of Appeal that it had initiated discussions with the Appellant with a view to helping the Appellant and the Intervener to reach an amicable solution and thereby resolve the present dispute. It further stated that at present it did not wish to submit further observations.
- 23. A copy of the documents submitted by the Agency was notified to the Appellant and the Intervener on 9 January 2015.
- 24. On 5 February 2015, the Board of Appeal invited the Agency and the Appellant to provide information on the outcome of their discussions related to a possible amicable solution. On 12 February 2015, the Agency informed the Board of Appeal that it had not been able to reach an agreement with the Appellant as regards a possible settlement. On the same date the Appellant submitted its response, indicating that it wished the proceedings before the Board of Appeal to continue.
- 25. On 19 February 2015, the responses of the Appellant and the Agency as regards the discussions on a possible settlement of the case were notified to the Intervener. On the same day, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure.
- 26. On 5 March 2015, both the Appellant and the Agency requested a hearing. Pursuant to Article 13 of the Rules of Procedure, the Board of Appeal informed the Parties on 26 June 2015 that an oral hearing was to be held on 21 October 2015.
- 27. On the same day, 26 June 2015, the Intervener was informed of the date of the hearing and the opportunity it provided to make oral submissions regarding the appeal. The Intervener was requested to inform the Board of Appeal whether it intended to attend the hearing. The Intervener did not respond to the invitation to the hearing.
- 28. The hearing was held on 21 October 2015 and was attended by representatives of the Appellant and the Agency. Interpretation from English to German, and *vice versa*, was provided for. At the hearing, the Parties made oral presentations and responded to questions asked by the Board of Appeal.

# Arguments of the Parties

#### The Appellant's arguments

- 29. The Appellant seeks the annulment of the Contested Decision and the revocation of the registration number assigned to the Intervener. The Appellant raises a single plea in law in support of its appeal, claiming that the Contested Decision was adopted in breach of the legal requirements set out in the REACH Regulation.
- 30. In support of its plea the Appellant argues that, when performing the completeness check provided for by Article 20(2), the Agency must ascertain that all the elements required, inter alia, by Articles 10 and 12 have been provided. The Appellant claims that the Agency should not have assigned a registration number to the Intervener

since the Intervener's registration dossier did not contain the information required by Articles 10 and 12. In particular, the Intervener's registration dossier did not contain any basic physicochemical and toxicological data, including any vertebrate animal studies, and was devoid of all relevant content. The Contested Decision therefore circumvented the principle of 'no data, no market' provided for by Article 5. This amounts to unequal treatment since undertakings that fulfil the requirements of the REACH Regulation are placed in the same situation as undertakings that deliberately circumvent the rules and exploit the gaps in the Agency's registration system.

31. The Appellant further argues that, under Article 11, all registrants of the same substance are obliged to register that substance jointly, or to become part of an existing joint submission if they register a substance when a joint submission already exists. By accepting a registration submitted outside the joint submission, the Contested Decision infringed Article 11. The Appellant further claims that, as a member of the existing joint submission for the Substance, lead registrant and owner of rights to data relevant to the registration, it is entitled to obtain from the Intervener adequate compensation for a share of the costs which it had to bear in the preparation of the joint submission. The Contested Decision therefore allowed the Intervener to circumvent the data sharing procedure and to avoid sharing the relevant costs, infringing Article 27.

## The Agency's arguments

- 32. The Agency claims that the appeal is inadmissible since the Appellant is neither the addressee of the Contested Decision, nor is the Contested Decision of direct and individual concern to the Appellant as required by Article 92(1).
- 33. With regard to whether the Appellant is directly concerned by the Contested Decision, the Agency argues that the fact that another registrant registered the Substance separately does not affect the Appellant's registration and places no additional rights or obligations on the Appellant. Its alleged rights regarding relevant information cannot lead to the conclusion that it is directly concerned by the Contested Decision. There is no evidence that the Intervener's dossier includes any reference to studies to which the Appellant holds rights. Moreover, the Agency argues that, contrary to the Appellant's assertions, the REACH Regulation does not oblige later registrants to share, with appropriate compensation, all the data submitted by previous registrants. There is no absolute right for previous registrants of a substance to be compensated under the REACH Regulation. The data sharing obligations merely preclude potential registrants from duplicating studies involving vertebrate animals. In addition, according to the Agency, there is no connection between the completeness check and data sharing obligations.
- 34. The Agency also disputes that the Appellant is individually concerned by the Contested Decision. It argues that the group of manufacturers and importers of the Substance is defined by abstract criteria and is an open group, the membership of which might vary over time. Therefore, the Appellant is not individually concerned by the Contested Decision insofar as it allows its addressee to manufacture and import the Substance. In addition, the Agency claims that the applicable provisions of the REACH Regulation do not foresee the participation of other registrants of the same substance in the completeness check procedure under Article 20. The completeness check procedure does not provide any person other than the person submitting the dossier with legal safeguards or procedural guarantees. The Agency therefore claims, with reference to paragraph 103 of the Order of the General Court in Case T-532/08, *Norilsk Nickel and Umicore* v *Commission*, EU:T:2010:353, that the Appellant does not enjoy a special

legal position capable of distinguishing it individually under the completeness check procedure. With regard to the Appellant's alleged right to compensation for data sharing, the Agency further argues that the Contested Decision does not affect the obligations of the registrants to share data or any rights to compensation for the cost of shared data. Consequently, the Appellant cannot be individually concerned by the Contested Decision due to an infringement of its alleged right to adequate compensation for a share of the costs which it had to bear in the preparation of the joint submission.

- 35. In addition, the Agency argues that the appeal is inadmissible since a third party cannot appeal against positive completeness check decisions under the REACH Regulation. According to Article 20(5), an appeal may be brought only against Agency decisions under Article 20(2), which only refers to the rejection of a registration. Article 20(5) does not refer to a decision under Article 20(3) which finds a registration to be complete and assigns a registration number to it.
- 36. As regards the substance of the case, the Agency argued in its written submissions that the Contested Decision fulfils all formal and substantive legal requirements for a completeness check decision under Article 20 and should therefore not be annulled. At the hearing, however, the Agency conceded that the Intervener's registration dossier does not satisfy the information requirements provided for by Articles 10 and 12. Nevertheless, according to the Agency, the completeness check procedure merely requires it to verify that the dossier contains the elements required under Article 20(2). The Agency is not obliged to verify the quality or adequacy of the provided information.

# The Intervener's arguments

- 37. The Intervener contests the Appellant's arguments relating to the Contested Decision and questions the admissibility of the appeal.
- 38. With regard to admissibility, the Intervener argues that the appeal was brought out of time and is therefore inadmissible.
- 39. Regarding the merits of the case, the Intervener submits that when registering the Substance it followed the registration procedure, for example by observing its duty to inquire prior to registration pursuant to Article 26(1), and submitted to the Agency all the necessary information for registration purposes. Contrary to the Appellant's claims, the dossier did not lack the necessary physicochemical and toxicological data.
- 40. The Intervener further argues that data sharing is not mandatory under Article 27(1) and that, since it has not requested any information from the previous registrants, Article 27(2) does not apply to it. Moreover, the registration dossier submitted by the Intervener did not include any information owned by the Appellant.
- 41. The Intervener also contends that it submitted the information required for registration purposes individually in accordance with Article 11(3)(a) and (c). In particular, the information and test results referred to by the Appellant are not necessary for the Intervener's registration of the Substance and it would be disproportionately costly for it to submit information jointly.

#### Reasons

42. Before examining the merits of the case, the Board of Appeal will address the claims of inadmissibility raised by the Agency and the Intervener.

# Admissibility

43. As a preliminary remark the Board of Appeal observes that, in accordance with Article 11(2) of the Rules of Procedure, if the Chairman does not decide on the admissibility of the appeal within the time limit laid down in Article 93(2), 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. In the present proceedings, the Board of Appeal will therefore first examine the Agency's claims and the Intervener's submissions as regards the inadmissibility of the appeal.

# (i) Time limit for bringing an appeal

- 44. The Intervener claims that the appeal is inadmissible since it was not lodged within the time period prescribed in Article 92(2).
- 45. The Agency has not raised any claim of inadmissibility concerning the time at which the present appeal was lodged at the Registry of the Board of Appeal.
- 46. The Appellant submits that the appeal was brought within the prescribed time period, calculated from the date on which it became aware of the Contested Decision.
- 47. As regards the Intervener's claim that the appeal was lodged out of time, the Board of Appeal observes that, according to Article 8(3) of the Rules of Procedure, submissions in an application to intervene shall be limited to supporting or opposing the remedy sought by one of the parties. It follows that an intervener must accept the proceedings before the Board of Appeal as it finds them at the time of the intervention (see, to that effect, Order of the General Court in Case T-673/13, *European Coalition to End Animal Experiments* v *ECHA*, EU:T:2015:167, paragraph 36) and that an intervener is, in general, not entitled to raise an objection of inadmissibility not raised by any of the parties (see, by analogy, Case C-313/90, *CIRFS and Others* v *Commission*, EU:C:1993:111, paragraph 22).
- 48. The Board of Appeal however notes that, according to the settled case-law of the Court of Justice of the European Union, the time limit for bringing an action for annulment is a matter of public policy since it was established in order to ensure that legal positions are clear and certain and to avoid any discrimination or arbitrary treatment in the administration of justice, and the judicature of the European Union must ascertain of its own motion whether it has been observed (see Joined Cases T-121/96 and T-151/96, *Mutual Aid Administration Services v Commission*, EU:T:1997:132, paragraphs 38 and 39). The Board of Appeal considers that the case-law above is applicable by analogy to the present proceedings (see Case A-005-2012, *SEI EPC ITALIA*, Decision of the Board of Appeal of 27 February 2013, paragraph 22).
- 49. In accordance with Article 92(2) of the German version of the REACH Regulation, an appeal 'shall be filed in writing to the Agency within three months of the notification of the decision to the person concerned, or in the absence thereof, within one month of the day on which it became known to the latter'.
- 50. Having regard to Article 92(2) and the case-law referred to in paragraph 48 above, the Board of Appeal will ascertain whether in the present case the Appellant observed the time limit for bringing the appeal against the Contested Decision.
- 51. The Board of Appeal notes that the Agency adopted the Contested Decision on 19 July 2013 and that the Appellant, who was not the addressee of the Contested Decision, lodged this appeal on 12 December 2013.

- 52. It is therefore necessary to determine on what date the Appellant became aware of the Contested Decision.
- 53. The Board of Appeal notes that registration decisions are notified individually to the concerned registrants and the Agency does not make them publicly available. However, certain information concerning registered substances, including the names of companies that have successfully registered a substance, is disseminated on the Agency's website in accordance with Article 119.
- 54. The Agency has submitted, without this being disputed by the Appellant, that the Intervener has been identified as being one of the registrants of the Substance on the Agency's dissemination website since 17 October 2013.
- 55. The Appellant claims that it became aware of the Intervener's registration through the dissemination website on 14 November 2013. In reply to a question of the Board of Appeal, the Agency stated that it 'has no means of verifying when the Appellant accessed the dissemination website and has no reason to doubt the truthfulness of the Appellant's statement.' The Agency has further submitted that 'the Contested Decision was not disseminated or otherwise publicised for valid reasons. Given that the Agency does not track individuals' use of the dissemination website, it cannot provide any evidence with regard to the publication or dissemination of the Contested Decision.' However, the Agency has also stated that while it does not make decisions on completeness checks available to the general public, the Agency does publish information about the registrants of substances on its dissemination website, provided that the registrant has not requested its identity to be treated as confidential. The Agency has explained that it can be inferred from the publication of a registrant's name on the dissemination website that it has submitted a complete registration, has received a decision from the Agency to this effect, and has been assigned a registration number.
- 56. As stated in the previous paragraph, the Appellant claims to have become aware of the Intervener's registration on 14 November 2013, and no evidence has been presented to rebut this claim. If this date is used as a starting point, the appeal was lodged less than one month after the Appellant became aware of the Contested Decision, namely on 12 December 2013. The appeal was therefore lodged within the time period laid down by Article 92(2).
- 57. The Board of Appeal notes that some language versions of Article 92(2), including the German version, provide that, in the absence of notification, an appeal must be filed *'within one month [...] of the day on which it became known'* to the person concerned. Other language versions, such as the English and French versions, instead provide for a time period of three months. The Board of Appeal observes that in the present case this discrepancy between the various language versions cannot affect the admissibility of the appeal, which was filed less than one month after the Appellant became aware of the Contested Decision.
- 58. In light of the above, the Board of Appeal concludes that the appeal was brought within the time limit provided by Article 92(2).

# (ii) Decision against which the appeal is lodged

59. The Agency argues that the Contested Decision is a decision confirming the completeness of the Intervener's registration dossier and assigning a registration number in accordance with Article 20(3) and, as such, it cannot be subject to appeal.

10 (21)

The Agency adds that, in accordance with Article 20(5), only decisions rejecting a registration under Article 20(2) can be appealed before the Board of Appeal.

- 60. The Appellant argues that the Contested Decision can be appealed in accordance with Article 91(1).
- 61. The Board of Appeal observes that Article 91(1) lists the decisions against which an appeal may be lodged. The list refers to '*Article 20*', without a reference to any of the paragraphs of that Article.
- 62. This can be contrasted with the references to other provisions mentioned in Article 91(1), such as 'Article 27(6)' and 'Article 30(2) and (3)'. Whilst Article 91(1) limits the decisions which may be appealed to certain specific paragraphs of the relevant Articles, this is not the case with respect to Article 20. The Board of Appeal considers that this indicates that any decision taken by the Agency pursuant to Article 20 may be subject to appeal proceedings before the Board of Appeal.
- 63. In the present proceedings, the Contested Decision confirmed the completeness of the Intervener's registration dossier in accordance with Article 20(2) and assigned a registration number for the Substance to the Intervener pursuant to Article 20(3). Since the decision was taken by the Agency pursuant to Article 20 it can be subject to appeal before the Board of Appeal.
- 64. In addition, the Board of Appeal notes that the Appellant argues that the Agency should not have found the registration submitted by the Intervener to be complete and should instead have taken the steps provided for under Article 20(2). In that case, the Agency would have adopted a decision on the basis of Article 20(2). Such a decision can be appealed in accordance with Article 20(5). The Board of Appeal considers that a possible error made by the Agency should not affect the scope of its competence. Therefore, the Contested Decision can be appealed before the Board of Appeal.
- 65. Considering the above, the Board of Appeal concludes that the Agency's claim that the Contested Decision cannot be appealed before the Board of Appeal must be dismissed.

# (iii) The Appellant's standing to bring this appeal

- 66. The Board of Appeal will next examine whether the Appellant has standing to bring this appeal. The Agency argues that since the Appellant is not directly and individually concerned by the Contested Decision the appeal should be declared inadmissible.
- 67. The Appellant claims that it is directly and individually concerned by the Contested Decision and therefore has standing to bring this appeal.
- 68. The Board of Appeal notes that under Article 92(1) '[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 Appellant is not the addressee of the Contested Decision it is for the Board of Appeal to examine whether the Contested Decision is of direct and individual concern to the Appellant within the meaning of this provision.
- 69. Article 92(1) contains a similar formulation to Article 230, paragraph 4, of the Treaty establishing the European Community (hereinafter the 'EC Treaty'), which was replaced, with slightly different wording, by Article 263, paragraph 4, of the Treaty on the Functioning of the European Union (hereinafter the 'TFEU'). The Board of Appeal consequently considers that when applying Article 92(1) it must be guided by the settled case-law of the Court of Justice of the European Union on the concepts of

direct and individual concern under Article 230, paragraph 4, of the EC Treaty and under the Article 263, paragraph 4, TFEU.

70. Before assessing whether the Contested Decision is of direct and individual concern to the Appellant, the Board of Appeal considers it necessary to examine the legal framework for joint submissions as established by the REACH Regulation. It will therefore first determine whether the Intervener was obliged to join the existing joint submission for the registration of the Substance, and subsequently analyse the contents and the effects of the Contested Decision with regard to the Appellant's legal situation.

The principle of 'one substance, one registration'

71. Article 11(1) provides as follows:

'When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 10(a)(viii) shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as "the lead registrant").

Each registrant shall subsequently submit separately the information specified in Article 10(a)(i), (ii), (iii) and (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) separately or whether one registrant is to submit this information on behalf of the others.'

72. Article 11(3) further provides:

'A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

(a) it would be disproportionately costly for him to submit this information jointly; or

(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

(c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.'

73. The Board of Appeal observes that Article 11 gives effect to one of the fundamental pillars of the REACH Regulation, namely that for each substance there should be only one joint submission (the principle of 'one substance, one registration'). This means that, if there is more than one registrant for a phase-in substance, the registrants should form a joint submission for the registration of that substance. Equally, if a subsequent registrant intends to register a substance for which there is already a joint submission, that registrant is required to join the existing joint submission for the substance. Article 11(3) does not allow a registrant to 'opt out' from a joint submission in its entirety by submitting a wholly separate registration for the same

substance. A registrant may submit the information for certain endpoints separately for the reasons listed in Article 11(3)(a) to (c), and only if it provides an explanation for doing so.

- 74. The conclusion that there must be only one joint submission for each substance is confirmed by the second and third sentences of Recital 33, which state that '[o]*ne of a group of multiple registrants should submit information on behalf of the others according to rules which ensure that all the required information is submitted, while allowing sharing of the costs burden. A registrant should be able to submit information directly to the Agency in certain specified cases.'*
- 75. This conclusion is also consistent with Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with the REACH Regulation (OJ L 3, 6.1.2016, p. 41; hereinafter the 'Implementing Regulation on joint submission of data and data-sharing'), which was adopted during the course of the present proceedings. In particular, Recital 14 and Article 3 of that Regulation clarify the obligations already established in the REACH Regulation (see paragraph 73 above) by stating that 'all registrants of the same substance are part of the same registration' and that 'a separate submission of the information referred to in Article 10(a), justified under Article 11(3) or 19(2) of [the REACH Regulation], is still part of the existing registration for that substance'. The Agency also indicated during these proceedings that it shares the view that the obligation to register jointly is unconditional and applies to all registrants of the same substance.
- 76. The Board of Appeal notes that, despite the fact that the inquiry submitted by the Intervener indicated otherwise, the Substance is a phase-in substance within the meaning of Article 3(20). The Board of Appeal further notes that it is undisputed that the Intervener submitted an individual registration despite the existence of a joint submission for the Substance. The Intervener argues that it submitted the information required for registration purposes individually in accordance with Article 11(3)(a) and (c) (see paragraph 41 above). However, the Board of Appeal considers that, even if the Intervener had explained its reasons for submitting information separately in its registration dossier, it would still have been obliged to join the joint submission for the Substance. Any disagreement with the Appellant, which is the lead registrant for the Substance, regarding the selection or cost of the relevant information should have been addressed either during data sharing negotiations, with the ensuing possibility of submitting a data sharing dispute to the Agency pursuant to Article 27, or by way of an 'opt out' from the relevant parts of the joint submission pursuant to Article 11(3), with the consequent obligation to explain the reasons for that 'opt out' in its registration dossier. The REACH Regulation provides for both of those possibilities within the framework of a joint submission.
- 77. The Board of Appeal recalls that the Intervener submitted a wholly separate and individual registration when there was already a joint submission for the Substance. The Board of Appeal further notes that, for the reasons laid out in paragraphs 73 and 74 above, every subsequent registrant of the Substance is obliged to become a member of the existing joint submission. Consequently, without examining at this stage the consequences of this finding on the legality of the Contested Decision, the Board of Appeal finds that the Intervener failed to comply with its obligation pursuant to Article 11 to become a member of the existing joint submission for the Substance.

Contents and effects of the Contested Decision

- 78. The Board of Appeal will next examine the contents and the effects of the Contested Decision. As explained above, the Board of Appeal notes that a registrant who intends to register a substance for which there is an existing joint submission must join the existing joint submission (Article 11). The new registrant must request from the previous registrants, including the lead registrant, information involving tests on vertebrate animals which it requires for the purposes of its registration and then make every effort to reach an agreement on the sharing of any such information (see Articles 26 and 27). Alternatively, it may explain why it is submitting certain information separately (see Article 11(3)).
- 79. The Board of Appeal further notes that the relationship between the joint submission obligation under Article 11 and the data-sharing provision in Article 27 is confirmed by the first sentence of Recital 33. That recital states that '[j]oint submission and the sharing of information on substances should be provided for in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals'. These objectives can be fulfilled only if a subsequent registrant of the same substance is required to join the existing joint submission with all the consequent duties and obligations that apply.
- 80. The Board of Appeal observes that in its first complaint to the Agency, dated 13 March 2013, the Appellant stated that there were 9 individual submissions. The number of individual submissions increased to 34 during the course of the written procedure, and further rose to 111 by the time of the hearing. This was not disputed by the Agency or the Intervener. The Board of Appeal notes that the intention of the legislator was that the REACH Regulation would, inter alia, ensure that all relevant data on a substance would be assessed in the preparation of joint submissions with the aim of ensuring a high level of protection of human health and the environment, and that the cost of the data would be shared between all joint registrants with the aim of minimising costs to help the competitiveness of the EU industry. It follows from this that, if there are many individual registrations of substances for which there are existing joint submissions, the consequences will be that the registration data set for the joint submission will be based on fewer data with possible implications for the protection of human health and the environment and that the cost of the data set will be shared between fewer companies, thereby increasing the costs to those companies in the joint submission.
- 81. The Contested Decision confirmed the completeness of the registration submitted by the Intervener and assigned a registration number despite the fact that the Intervener's registration was not part of the existing joint submission for the Substance. The Contested Decision thereby allowed the Intervener to circumvent its obligations under the REACH Regulation and, as a result, deprived Articles 11 and 27 of their effect. Consequently the Intervener was able to avoid its data sharing obligations and the Appellant was unable to perform its obligations vis-à-vis other registrants of the same substance regarding data sharing.
- 82. The Contested Decision thereby circumvented the obligations in the REACH Regulation that give force to the objective that testing on vertebrate animals should be reduced and that the sharing of the costs burden of registration among the registrants of a substance shall take place in a fair, transparent and non-discriminatory way (Recital 33 and Article 27). In addition, it undermined the underlying goal of the joint submission obligation, namely that the information provided on a substance should allow the relevant actors to form as complete a picture as possible of the hazards posed by the substance, its uses on the European Union market, and the risks involved therein.

#### Direct and individual concern

- 83. With regard to direct concern within the meaning of Article 263, paragraph 4, TFEU, the Court of Justice of the European Union has consistently held that the contested act must directly affect the legal situation of an applicant and leave no discretion to the authorities responsible for implementing that act, such implementation being purely automatic and resulting from European Union law alone, without the application of other intermediate rules (Case C-132/12 P, *Stichting Woonpunt and others v Commission*, EU:C:2014:100, paragraph 68 and case-law cited). That rule also applied under Article 230 of the EC Treaty which was in force at the time the REACH Regulation was adopted (see Case C-519/07 P, *Commission v Koninklijke FrieslandCampina*, EU:C:2009:556, paragraph 48).
- The Board of Appeal notes that the Appellant is the lead registrant of the joint 84. submission for the Substance. Moreover, the Appellant has stated, without being contradicted on that point by the Agency or the Intervener, that it is the 'sole owner of rights to the study results' relevant to the joint submission for the Substance and contained in the lead registration dossier, including studies conducted on vertebrate animals. As this statement has not been disputed, and as no indication to the contrary has been submitted during the course of these proceedings, the Board of Appeal accepts the Appellant's statement for the purposes of this appeal. However, this does not prejudice any conclusions which the Agency may draw from any future examination of the quality of the information contained in the Appellant's registration dossier pursuant to a compliance check under the dossier evaluation procedure. Equally, this does not compel any registrant to share and pay for the Appellant's data if those data are not required for the purposes of its registration, and does not affect the possibility for other registrants to 'opt out' from parts of the joint submission under Article 11(3).
- 85. The Board of Appeal recalls that the Appellant, in its capacity as lead registrant for the Substance, had already submitted a complaint to the Agency before the adoption of the Contested Decision, pointing out that individual submissions for the registration of the Substance had been made outside the joint submission and arguing that some individual registration dossiers were devoid of any real content (see paragraph 3 above). The Board of Appeal also notes that in the present case the Agency stated at the hearing that 'not all the elements required [by Article 20(2)] were provided' by the Intervener in its registration.
- 86. The Board of Appeal has already found, at paragraphs 80 to 82 above, that the Contested Decision deprived Articles 11 and 27 of their effect. As it is uncontested that the Appellant is the 'sole owner of rights to the study results' relevant to the joint submission for the Substance and contained in the lead registration dossier, including studies conducted on vertebrate animals, the Contested Decision thereby affected the Appellant's legal position by allowing the Intervener to register the substance outside the joint submission, and therefore enabling it to circumvent its obligations as a joint registrant with regard to data and cost sharing.
- 87. In addition, the Board of Appeal notes that although the inquiry submitted by the Intervener indicated that it concerned a 'non-phase-in substance', the Agency correctly identified that the Substance was a 'phase-in substance' within the meaning of Article 3(20) and that a joint submission for the Substance had already been submitted. Consequently, the Agency informed the Appellant about the inquiry made by the Intervener in accordance with the third subparagraph of Article 26(3). As a result, the Appellant was itself subject to obligations under Articles 11 and 27. The

Agency does not dispute that the Appellant attempted to establish contact with the Intervener, indicating that it had relevant vertebrate animal studies available and offering to send information regarding the joint submission and the letter of access. In doing so, the Appellant was acting in response to its obligations pursuant to Articles 11 and 27 as lead registrant and holder of rights to data on the Substance which were derived from testing on vertebrate animals.

- 88. Consequently, the Contested Decision directly affected the Appellant's legal situation as lead registrant and holder of rights to data relevant to the registration of the substance, including data derived from tests on vertebrate animals.
- 89. The Board of Appeal also notes that the Contested Decision does not require any implementation. For the reasons stated in paragraphs 83 to 88 above, the Board of Appeal finds that the Contested Decision is of direct concern to the Appellant within the meaning of Article 92(1).
- 90. The Board of Appeal will next examine whether the Contested Decision was also of individual concern to the Appellant.
- 91. Regarding individual concern within the meaning of Article 263, paragraph 4, TFEU, according to established case-law, persons other than those to whom a decision is addressed may only claim to be individually concerned if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed (see Case 25/62, *Plaumann* v *Commission*, EU:C:1963:17, p. 107, and Joined Cases C-71/09 P, C-73/09 P and C-76/09 P, *Comitato 'Venezia vuole vivere' and Others* v *Commission*, EU:C:2011:368, paragraph 52 and case-law cited). Moreover, where a contested measure affects a group of persons who were identified or identifiable when that measure was adopted by reason of criteria specific to the members of the group, those persons might be individually concerned by that measure inasmuch as they form part of a limited class of traders (see Case 11/82, *Piraiki-Patraiki and Others* v *Commission*, EU:C:1985:18, paragraph 31; Case C-519/07 P, *Commission* v *Koninklijke FrieslandCampina*, EU:C:2009:556, paragraph 54).
- 92. The Board of Appeal recalls that it was not contested during the course of these proceedings that the Appellant is the lead registrant for the Substance and the 'sole owner of rights to the study results' relevant to the joint submission for the Substance, including tests involving vertebrate animals (paragraph 84 above). The Contested Decision relieved the Intervener of the obligation to join the joint submission, thereby depriving Articles 11 and 27 of their effect (see paragraphs 80 to 82 above). As a result, the Contested Decision affected those registrants who had joined the joint submission for the Substance, including the Appellant. Those registrants, whose names and identity can be established, form a limited class of persons who are affected by the Contested Decision and are therefore individually concerned.
- 93. The conclusion that the Appellant is individually concerned by the Contested Decision is not called into question by the Agency's argument that the Contested Decision does not affect the Appellant more than any other undertaking which might register the Substance now or at some time in the future.
- 94. The Board of Appeal considers that there are objective factors which distinguish the Appellant from any other undertaking. As the lead registrant for the Substance and the 'sole owner of rights to the study results' relevant to the joint submission for the Substance, including tests involving vertebrate animals, the Appellant has a particular

interest in ensuring that the other registrants of the Substance fulfil their obligations under Articles 11 and 27. The Contested Decision deprived the Appellant of the possibility to share the cost of data obtained through testing on vertebrate animals with the Intervener. As a result, the Contested Decision is of individual concern to the Appellant.

- 95. In light of the above considerations, the Board of Appeal finds that the Contested Decision is of direct and individual concern to the Appellant. The arguments raised by the Agency in this regard are therefore dismissed.
- 96. The Board of Appeal concludes that this appeal was brought within the time limit prescribed by Article 92(2), it is directed against a challengeable decision under Article 91(1), and that the Contested Decision is of direct and individual concern to the Appellant. The appeal is therefore admissible.

#### Substance

97. The Appellant raises a single plea in support of its appeal, claiming that the Contested Decision was adopted in breach of the legal requirements set out in the REACH Regulation. The plea consists of two parts which will be examined separately.

# (i) The first part of the plea alleging a breach of Article 20 in conjunction with Articles 10 and 12

- 98. The Appellant argues that the Agency breached Article 20(2) by finding the Intervener's registration to be complete, and assigning it a registration number, despite the fact that it did not contain the information required by Articles 10 and 12.
- 99. The Agency argues that, when performing the completeness check under Article 20(2), it is not obliged to verify the quality or the adequacy of any data or justifications submitted. As the Intervener inserted text into all the necessary fields in its registration dossier and provided a chemical safety report, its registration was considered to be complete. The Agency adds that the completeness check process is fully automated from the point of receipt of the registration dossier to the issuing of the decision. The IT system used for performing completeness checks is not designed to verify whether the text inserted by registrants in their registration dossiers is meaningful but merely if information exists.
- 100. The Intervener claims that it has fulfilled all the requirements of the REACH Regulation when registering the Substance.
- 101. At the outset, the Board of Appeal observes that pursuant to Article 75 and Recital 15 it is the Agency's responsibility to ensure the effective management of the technical scientific and administrative aspects of the REACH Regulation and to ensure consistency at EU level in relation to these aspects. This responsibility includes the registration process and in particular the completeness check pursuant to Article 20(2). The first indent of Article 20(2) provides more specifically that '[t]he Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required [inter alia] under Articles 10 and 12 [...] have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.'
- 102. Pursuant to Article 10(a)(vi) and (vii), a registration dossier shall include a technical dossier including study summaries of the information derived from the application of Annexes VII to XI and robust study summaries of the information derived from the

application of Annexes VII to XI, if required under Annex I. Article 12 further specifies the minimum physicochemical, toxicological and ecotoxicological information that must be included in the technical dossier referred to in Article 10(a) under points (vi) and (vii), depending on tonnage per year.

- 103. The Board of Appeal observes that it follows from the provisions referred to in paragraphs 101 and 102 above, that the Agency is responsible for the examination of the completeness of a registration dossier and the assignment of a registration number to a registrant if the registration is complete. It also follows that the Agency is under an obligation to examine whether a registration dossier includes the elements required by Articles 10 and 12.
- 104. The Intervener claims that it has submitted all the required information and that its dossier is therefore complete. It has, however, neither explained that assertion nor submitted any information capable of supporting it. The Appellant claims that an examination of the parts of the Intervener's registration which were published on the Agency's dissemination website indicates that the Intervener's registration does not include basic physicochemical and toxicological data, including any vertebrate animal studies, and is devoid of all relevant content.
- 105. In response to a written question from the Board of Appeal, the Agency conceded that the Intervener's registration dossier 'contains text that clearly does not satisfy the information requirements' under Articles 10 and 12. The Agency further accepted at the hearing that 'not all the elements required [by Article 20(2)] were provided' by the Intervener. The Agency also conceded that there are certain flaws in the automated system which allowed the Intervener to benefit from the 'inconsistent use' of the 'disregarded study' flag in the automated system for the submission of registration dossiers.
- 106. The Agency pointed out at the hearing that the use of an automated system for the completeness check is a 'practical necessity' and helps to ensure the efficient processing of registrations. The Board of Appeal notes, however, that the fact that the IT application used by the Agency cannot verify the presence of all the elements required under Articles 10 and 12 does not exonerate the Agency from its obligation to check the completeness of dossiers in accordance with Article 20(2).
- 107. According to the first subparagraph of Article 20(2), '[t]he completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.' Nevertheless, the Board of Appeal considers that ascertaining that all the elements required under Article 20(2) are provided in a registration dossier does not constitute an assessment of the quality or the adequacy of any information submitted.
- 108. Equally, the fact that the second subparagraph of Article 20(2) provides strict deadlines for completeness checks to be conducted does not alter the Agency's obligation to check that the submitted registration dossiers are complete in accordance with the first subparagraph of Article 20(2).
- 109. For the reasons laid out in paragraphs 101 to 108 above, the Board of Appeal finds that in the present case the Agency has failed to adequately examine the completeness of the Intervener's dossier with regard to the elements required by Articles 10 and 12, as required by Article 20(2). The first part of the Appellant's plea must therefore be upheld.
- 110. For the sake of completeness the Board of Appeal will also examine the second part of the plea raised by the Appellant.

# (ii) The second part of the plea alleging a breach of Article 20 in conjunction with Article 11

- 111. The Appellant argues that the Contested Decision was adopted in breach of Article 11, which requires all registrants of the same substance to submit a joint registration, or to become part of an existing joint submission, as the case may be. It submits that the Agency was obliged to verify that this obligation had been respected before assigning a registration number to the Intervener.
- 112. The Agency submits that at the time of the adoption of the Contested Decision it could not reject a registration under Article 20 on the basis of a breach of Article 11. It argues that the principle of *'one substance, one registration'* is not one of the elements which the Agency is required to verify during the course of the completeness check procedure under Article 20(2). The Agency further argues that at the time of the adoption of the Contested Decision it was not competent to reject individual registrations which were submitted in breach of that principle. The Agency added at the hearing that it could only do so once an implementing regulation to that effect is adopted by the Commission and enters into force.
- 113. The Board of Appeal has already found, at paragraph 77 above, that under Article 11, the Intervener was obliged to join the existing joint submission for the registration of the Substance.
- 114. The Board of Appeal will now examine whether the Agency could, at the time of the adoption of the Contested Decision, regard the Intervener's registration as being incomplete as a result of it not being submitted as part of the joint submission and take the steps provided for under the third and fourth subparagraphs of Article 20(2).
- 115. The Board of Appeal observes that, as the Agency correctly points out, Article 11 is not expressly included in the first subparagraph of Article 20(2) which lists the necessary information to be provided for a registration to be complete. It must therefore be determined whether the Agency was nevertheless competent, and obliged, to ascertain whether the Intervener's registration complied with Article 11 and to take the steps prescribed by Article 20(2) including, if appropriate, the rejection of the Intervener's registration.
- 116. The Board of Appeal recalls that the first subparagraph of Article 20(2) refers to Article 10 in the following terms: 'The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 [...] have been provided.'
- 117. The Board of Appeal observes that Article 10(a)(i) lists among the data to be required and checked by the Agency, for the purposes of the completeness check, 'the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI'.
- 118. The Board of Appeal notes that Section 1 of Annex VI, '*General registrant information*', includes information regarding the '*[j]oint submission of data*' as listed in Section 1.2. Section 1.2 of Annex VI provides as follows:

'Articles 11 or 19 foresee that parts of the registration may be submitted by a lead registrant on behalf of other registrants.

In this case, the lead registrant shall identify the other registrants specifying:

- their name, address, telephone number, fax number and e-mail address,

- parts of the present registration which apply to other registrants.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

19 (21)

Any other registrant shall identify the lead registrant submitting on his behalf specifying:

- his name, address, telephone number, fax number and e-mail address,

- parts of the registration which are submitted by the lead registrant.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.'

- 119. The Board of Appeal therefore considers that the name and contact information of the lead registrant and the parts of the registration which are submitted by the lead registrant are included in the 'elements required under [Article] 10'. If a joint submission exists, any consequent registrant of the same substance must therefore identify, inter alia, the lead registrant in their registration dossier. The Agency is consequently under a duty to verify whether an individual registrant has submitted information regarding the lead registrant for a joint submission for the relevant substance, and whether it has provided the information required in that regard by Section 1.2 of Annex VI. If the relevant elements of a registration are not provided the Agency must deem the registration to be incomplete and take the steps prescribed by the third and fourth subparagraphs of Article 20(2).
- 120. The Board of Appeal observes, in addition, that the principle of 'one substance, one registration' underpins the operation of Titles II and III of the REACH Regulation. In that light, the Board of Appeal considers that under Article 20 registrants can and should be prevented from submitting registrations which are not part of an existing joint submission for the same substance.
- 121. In the present case, it is uncontested that the Intervener submitted a separate registration for the Substance. The Board of Appeal has found at paragraph 77 above that this contravened the requirement for 'one substance, one registration'. The Agency, in light of the above, failed to ensure that the Intervener's registration adhered to this requirement.
- 122. This conclusion is consistent with the Implementing Regulation on joint submission of data and data-sharing, which was adopted during the course of the present proceedings. Recital 12 of that Regulation states that '[t]he principle of "one substance, one registration" should be reinforced by emphasising the role of the Agency in ensuring that all submissions of information regarding the same substance are part of the same registration'. It is clear from the quoted Recital that the Implementing Regulation on joint submission of data and data-sharing merely seeks to clarify the existing legal framework established by the REACH Regulation.
- 123. Contrary to the Agency's argument, the Board of Appeal observes that no implementing act could amend or supplement the Agency's powers to verify compliance with Article 11 under the completeness check process if those powers were not already provided for in the REACH Regulation (see to that effect Case C-88/14, *Commission* v *Parliament and Council*, EU:C:2015:499, paragraph 31). The Board of Appeal considers, in any event, that whilst the clarification in the Implementing Regulation on joint submission of data and data-sharing may be helpful, there was no need for an extension of the Agency's powers. Firstly, this is because an implementing act cannot grant new or additional powers and, secondly, because Articles 10, 11 and 20, read together with Section 1 of Annex VI, are sufficient in themselves to empower and require the Agency to reject registrations made outside an existing joint submission.
- 124. For the reasons given above, the Board of Appeal finds that the Contested Decision breaches Article 20 in conjunction with Article 11 since the Agency should not have

deemed the Intervener's registration for the Substance to be complete when it was not part of the existing joint submission for the Substance. The second part of the plea should therefore also be upheld.

- 125. On the basis of all of the above, the Contested Decision is annulled. The case is remitted to the competent body of the Agency for further examination.
- 126. For the sake of completeness, the Board of Appeal observes that the annulment of the Contested Decision in effect amounts to the revocation of the registration number assigned to the Intervener's registration pursuant to Article 20(3). In accordance with the case law of the Court of Justice of the European Union an advantageous decision may be revoked, even retroactively, where it rests on wrong or incomplete information from the persons concerned, provided doing so does not infringe the principles of legal certainty or legitimate expectations (see, to that effect, Case C-500/99 P, *Conserve Italia* v *Commission*, EU:C:2002:45, paragraph 90; Case C-90/95 P, *De Compte* v *Parliament*, EU:C:1997:198, paragraph 35 and the case-law cited).
- 127. In this context, the Board of Appeal considers that the annulment of the Contested Decision does not automatically entail the rejection of the registration submitted by the Intervener on 16 July 2013. Rather, the Agency is required to undertake a fresh completeness check of the submitted registration in accordance with Article 20(2) in order to ensure inter alia that the registration complies with Articles 10 and 12. In accordance with the third subparagraph of Article 20(2), the Agency is to inform the Intervener of the elements which are missing in order for its dossier to be complete, and set a reasonable deadline for the provision of the relevant information. The Board of Appeal further observes that if the Intervener submits the registration is found to be complete, then, according to Article 20(3), the registration date will be the same as the submission date, that is to say 16 July 2013. In those circumstances, the Agency in is a position to ensure that legal certainty and any legitimate expectations which the Intervener may entertain as to the legality of the Contested Decision are adequately safeguarded.

## Refund of the appeal fee

- 128. 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.
- 129. As the Board of Appeal has found in favour of the Appellant, the appeal fee shall be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls Decision SUB-D-2114256759-32-01/F, adopted by the European Chemicals Agency on 19 July 2013.
- 2. Remits the case to the competent body of the Agency for further examination.
- 3. Orders the refund of the appeal fee.

Mercedes ORTUÑO Chairman of the Board of Appeal

Alen MOČILNIKAR Registrar of the Board of Appeal