EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

9 April 2019

(Dossier evaluation – Compliance check – Registration dossier update during the decision–making procedure – Cut-off points for considering dossier updates – Legal certainty – Duties of the Agency)

Case number	A-001-2018
Language of the case	English
Appellant	BrüggemannChemical, L. Brüggemann GmbH & Co. KG, Germany
Representative	Martin Ahlhaus Noerr LLP, Germany
Intervener	The European Coalition to End Animal Experiments ('ECEAE'), United Kingdom
Contested Decision	CCH-D-2114373456-42-01/F of 10 November 2017 adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 41(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. On 28 January 2015, the Agency published a news alert (ECHA/NA/15/02) entitled '*ECHA tightens its practice on dossier updates*'. In that news alert the Agency announced that: '*[t]o shorten processing time, [the Agency] will no longer take into account dossier updates after the draft decision on a compliance check has been sent to the registrant for comments*'.

2. In July 2015, the Agency published version 1.1 of Practical Guide 12, '*How to communicate with ECHA in dossier evaluation*' ('Practical Guide 12'). Page 19 of Practical Guide 12 includes the following instructions on updates to registration dossiers during the compliance check decision-making procedure:

   '*Since 2015, if no reference is made in the registrant's comments [on the draft decision] submitted using the webform, [the Agency] does not normally take into account dossier updates in the process of adopting compliance check decisions to allow for efficient decision-making in the timelines set by the REACH Regulation. That means that after the draft decision has been notified to the registrant for comments no updates received will normally be taken into account for the adoption of the taken decision*'.

3. On 1 December 2015, pursuant to Article 41(1) of the REACH Regulation[1], the Agency initiated a compliance check of the Appellant's registration dossier for sodium hydroxymethanesulphinate (EC number 205-739-4, CAS number 149-44-0; 'the Substance').

Draft decision and the Appellant's comments

4. On 14 December 2015, the Agency sent a draft decision to the Appellant (the 'draft decision'). The draft decision requires the Appellant to submit information on:

   1. Carcinogenicity study (Section 8.9.1. of Annex X; test method: OECD TG 451), in rats, oral route;

   2. Pre-natal developmental toxicity ('PNDT') study (Section 8.7.2. of Annex X; test method: EU B.31/OECD TG 414) in a second species (rabbits), oral route; and

   3. Extended one-generation reproductive toxicity study ('EOGRTS') (Column 2 of Section 8.7.3. of Annex X; test method: EU B.56/OECD TG 443) in rats, oral route, according to the following study-design specifications:
      - At least two weeks premating exposure duration for the parental (P0) generation;
      - Dose level setting shall aim to induce some toxicity at the highest dose level;
      - Cohort 1A (Reproductive toxicity);
      - Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;
      - Cohorts 2A and 2B (Developmental neurotoxicity); and
      - Cohort 3 (Developmental immunotoxicity).

5. The draft decision states that it was prepared on the basis of the Appellant's registration dossier as last updated on 9 January 2015.

6. According to the cover note to the draft decision, '*[the Agency] does not take into account any dossier updates after the notification of this draft decision under Article 50(1) […]. Any such update will be examined by [the Agency] after the deadline set in the adopted decision has passed […]*'.

[1] All references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise.

7. On 3 February 2016, in accordance with Article 50(1), the Appellant submitted comments to the Agency on the draft decision.

8. In its comments on the draft decision in relation to the request to provide information on a carcinogenicity study the Appellant argued, amongst other things, that the conditions of Section 8.9.1. of Annex X had not been met because the Substance '*has neither a widespread dispersive use nor is there evidence of frequent or long-term human exposure*'. The Appellant explained that its registration dossier, as last updated on 9 January 2015, did not reflect the actual uses of the Substance. The Appellant added that '*the life-cycle of the [Substance] as well as the complete risk assessment as contained in the CSR [chemical safety report] will be revised in another dossier update as soon as possible*'.

9. With regards to the requirements to provide information on a PNDT study and an EOGRTS, the Appellant requested the Agency to take into account the revised life-cycle of the Substance as well as the fact that the Substance is classified as a germ cell mutagen category 2 and appropriate risk management measures for a substance with this hazard classification are in place.

Proposals for amendment

10. On 8 June 2017, pursuant to Article 51(1), the Agency notified the draft decision to the Member State competent authorities ('MSCAs') for their comments. Proposals for amendment were received from one MSCA. In one of the proposals for amendment it was suggested that the Appellant should be requested to provide an assessment of potential germ cell mutagenicity pursuant to Column 2 of Section 8.4. of Annexes IX and X. It was argued in the proposal for amendment that the studies required in the draft decision should be deferred pending a germ cell mutagenicity assessment. It was added that classification of the Substance as germ cell mutagen category 1A or 1B and the subsequent implementation of appropriate risk management measures would negate the need for the testing requested in the draft decision.

Appellant's observations on the proposals for amendment

11. On 14 August 2017, the Appellant provided observations on the proposals for amendment. The Appellant expressed its agreement with the proposal for amendment that it should be requested to provide an assessment of the potential germ cell mutagenicity of the Substance. The Appellant also stated that:

'[The] initial life-cycle in the dossier was obsolete and had to be completely revised as it did not reflect the actual use scenarios for the registered substance. [...] The revised life-cycle and the updated exposure and risk assessment now clearly demonstrate that the [Substance] has no widespread use and that there is no evidence of frequent or long-term human exposure [...]. The revised dossier contains, therefore, also a newly generated waiver for [the carcinogenicity] endpoint using the aforementioned conditions as scientific rationale'.

Appellant's dossier update

12. On 16 August 2017, the Appellant submitted a dossier update. In its dossier update, the Appellant amended the descriptions of the uses of the Substance.

Adoption of the Contested Decision

13. Between 12 and 14 September 2017, the Member State Committee (the 'MSC') reached unanimous agreement on the Contested Decision.

14. On 10 November 2017, the Agency adopted the Contested Decision requiring the Appellant to submit the same information as that set out in the draft decision. The Appellant was required to provide information on:

1. Carcinogenicity study (Section 8.9.1. of Annex X; test method: OECD TG 451), in rats, oral route;
2. PNDT study (Section 8.7.2. of Annex X; test method: EU B.31/OECD TG 414) in a second species (rabbits), oral route; and
3. EOGRTS (Column 2 of Section 8.7.3. of Annex X; test method: EU B.56/OECD TG 443) in rats, oral route, according to the following study-design specifications:
   - At least two weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting shall aim to induce some toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;
   - Cohorts 2A and 2B (Developmental neurotoxicity); and
   - Cohort 3 (Developmental immunotoxicity).

15. According to the cover letter to the Contested Decision '*[the] decision was adopted without considering any dossier updates submitted after the draft decision was notified to you following the procedure in Article 50(1) […]. Any update submitted after this date concerning the requirement(s) addressed by the enclosed decision will be examined by [the Agency] only after the deadline established in the enclosed decision has passed*'.

Procedure before the Board of Appeal

16. On 12 February 2018, the Appellant lodged this appeal.
17. On 13 April 2018, the Agency lodged its Defence.
18. On 15 June 2018, the Appellant lodged its observations on the Defence and replies to questions from the Board of Appeal.
19. On 29 June 2018, ECEAE was granted leave to intervene in support of the Appellant.
20. On 10 August 2018, the Agency lodged its observations on the Appellant's observations on the Defence and replies to questions from the Board of Appeal.
21. On 14 September 2018, the Intervener lodged its statement in intervention.
22. On 3 October 2018, the Appellant and the Agency lodged their respective observations on the statement in intervention.
23. On 4 October 2018, the Appellant and the Agency lodged their respective replies to additional questions from the Board of Appeal.
24. On 21 November 2018, a hearing was held at the Appellant's request. At the hearing, the Parties and the Intervener made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

25. The Appellant requests that the Board of Appeal:
    1. annuls the requirements in the Contested Decision to provide information on a carcinogenicity study and a PNDT study;
    2. partially annuls the requirement to provide information on an EOGRTS, insofar as it requires the extension of cohort 1B to include the F2 generation; and
    3. orders the refund of the appeal fee.
26. If the appeal is found to be inadmissible or is dismissed, the Appellant requests the Board of Appeal to amend the deadline set in the Contested Decision to take into account the suspensive effect of the appeal.

27. The Intervener supports the request to annul the requirement to provide information on a carcinogenicity study.

28. The Agency requests the Board of Appeal to dismiss the appeal in its entirety as unfounded.

Reasons

29. In relation to all three information requirements in the Contested Decision, the Appellant raises the following pleas in law:

    1. The Agency breached the principle of legal certainty as the rule that registration dossier updates will not be taken into account for the purposes of the final decision was not clear and precise nor did the Agency make that rule known to the Appellant in due time; and

    2. The Agency breached the principle of good administration by failing to take into account the dossier update of 16 August 2017.

30. In relation to the request to provide information on a carcinogenicity study, the Appellant raises the following additional pleas in law:

    1. The conditions set out in Column 2 of Section 8.9.1. of Annex X for requesting a carcinogenicity study are not met following the dossier update of 16 August 2017;

    2. As the uses triggering the requirement for a carcinogenicity study have been removed from the registration dossier, the request is deprived of a legal basis and is disproportionate. Pursuant to Article 50(3), no further information may be requested with respect to a substance where a registrant ceases to manufacture or import the substance. That provision should be applied by analogy to situations where a manufacturer ceases certain uses of the substance concerned; and

    3. As the uses triggering the requirement for a carcinogenicity study have been removed from the registration dossier, the Agency breached Article 25(1) according to which testing on vertebrate animals should be undertaken only as a last resort.

31. In relation to the request to provide information on a PNDT study, the Appellant raises the following additional plea in law. The Agency breached the principle of non-discrimination for data and cost sharing set out in the REACH Regulation and Commission Implementing Regulation (EU) 2016/9[2]. This is because the PNDT study could have been requested under Section 8.7.2. of Annex IX, rather than Section 8.7.2. of Annex X, and therefore been applicable also to registrants in the joint submission at the 100 to 1 000 tonnes per year tonnage band.

The Agency breached the principle of legal certainty

Arguments of the Appellant

32. The Appellant argues that, in accordance with the principle of legal certainty, obligations must be clear and precise and clearly brought to the attention of those concerned.

33. The Appellant states that it was informed of the deadline to submit dossier updates that would be taken into account in the decision-making procedure (the 'cut-off point') on the same date as it received the draft decision. The cut-off point was the same date the Appellant received the draft decision. The date the Appellant received the draft decision, the date the Appellant was informed of the cut-off date, and the date of the cut-off point were all therefore the same (see paragraphs 4 and 6 above).

[2] Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with the REACH Regulation (OJ L 3, 6.1.2016, p. 41).

34. The Appellant argues that, in accordance with the Agency's Practical Guide 12 (see paragraph 2 above), updates to registration dossiers which are indicated in the comments to a draft decision will be taken into account by the Agency in the decision-making procedure. The Appellant states that it clearly informed the Agency in its comments on the draft decision that it would update its dossier. In accordance with Practical Guide 12, the Agency should therefore have taken into account the Appellant's dossier update of 16 August 2017.

Arguments of the Agency

35. The Agency argues that it announced in a news alert on 28 January 2015 (see paragraph 1 above) that a new cut-off point had been put in place. The Agency also communicated the cut-off point to the Appellant in the letter accompanying the draft decision in a clear, precise and timely manner.

36. The Agency argues that registrants are obliged to keep their dossiers up-to-date. Pursuant to Article 22(1), registrants must update their registration dossiers without undue delay with relevant new information. In this case the Appellant failed to do so.

37. The Agency argues that the Substance was included on the Community Rolling Action Programme ('CoRAP') in 2015. Therefore the Appellant should have been aware that a compliance check may follow and updated its dossier before the draft decision was received.

38. The Agency argues that the Board of Appeal confirmed in its decisions in Case A-017-2014, *BASF SE,* and Case A-001-2014, *CINIC Chemicals Europe*, that the Agency may set a cut-off point for assessing dossier updates in the decision-making procedure. The Agency argues that, in the interests of administrative efficiency, it is necessary to set a cut-off point to reduce the processing time of compliance check decisions. The Agency argues that the cut-off point set in this case is appropriate having regard to the fact that registrants can include the content of any dossier updates in their comments on the draft decision and the Agency will take those comments into account.

39. The Agency argues that, in Case A-001-2014, *CINIC Chemicals Europe*, the Board of Appeal found that the Agency only had to take into account information received after the cut-off point set in the decision-making procedure when that information was substantial and new. Since the Appellant's dossier update of 16 August 2017 did not contain substantial new information*,* the Agency was not required to take that information into account in the decision-making procedure leading to the Contested Decision.

Arguments of the Intervener

40. The Intervener argues that the Agency unlawfully exercised its discretion by refusing to consider the Appellant's dossier update of 16 August 2017. In doing so, the Agency failed to take into account '*all relevant considerations*', including the obligation under Article 25 to ensure that testing on vertebrate animals is a last resort.

41. The Intervener argues that the Agency failed to apply the criteria set by the Board of Appeal in Case A-001-2014, *CINIC Chemicals Europe*, as the dossier update constitutes substantial new information and therefore should have been taken into account. Since the MSC did not consider the dossier update of 16 August 2017, it is not known whether that update would have influenced its decision-making.

42. The Intervener argues that applying the date of sending the draft decision to registrants for comments as an absolute cut-off point is contrary to Practical Guide 12, assurances made by the Agency in letters addressed to the Intervener, and the Board of Appeal's decisions in Case A-001-2014, *CINIC Chemicals Europe* and Case A-017-2014, *BASF SE*.

Findings of the Board of Appeal

43. The Appellant argues that the Agency breached the principle of legal certainty as the rule that registration dossier updates will not be taken into account for the purposes of the final decision was not clear and precise nor did the Agency make that rule known to the Appellant in due time.

44. Registrants must ensure that they are aware of the obligations applicable to them. However, for reasons of legal certainty, every act of the administration which produces legal effects should be clear and precise so that the person concerned is able to know without ambiguity what his rights and obligations are and to take steps accordingly (see judgment of 1 October 1998, *Langnese-Iglo* v *Commission*, C-279/95 P, EU:C:1998:447, paragraph 78; see also Case A-008-2015, *Evonik Degussa*, Decision of the Board of Appeal of 12 October 2016, paragraph 36). Those acts must be brought to the notice of those concerned in such a way that they can ascertain exactly the time at which the act comes into being and begins to have legal effects (see, by analogy, judgment of 22 January 1997, *Opel Austria* v *Council*, T-115/94, EU:T:1997:3, paragraph 124).

45. The REACH Regulation does not foresee a cut-off point. The cut-off point has been adopted by the Agency for reasons of administrative efficiency (see paragraph 38 above).

46. In the news alert of 28 January 2015 (see paragraph 1 above), the Agency explained that it had put in place a new cut-off point. Prior to this time, the cut-off point applied by the Agency had been the date on which the draft decision is sent to the MSCAs for proposals for amendment. The Agency announced in the news alert that it would '*no longer take into account dossier updates after the draft decision on a compliance check has been sent to the registrant for comments*'. There is no indication in the news alert that dossier updates received after this new cut-off point will, or may exceptionally, be taken into account.

47. The Agency also explained its new approach to the use of the cut-off point in a practical guide. In Practical Guide 12 published in July 2015, the cut-off point is expressed differently. According to Practical Guide 12 (page 19):

    '*Since 2015, <u>if no reference is made in the registrant's comments</u> submitted using the webform, <u>[the Agency] does not normally</u> take into account dossier updates in the process of adopting compliance check decisions to allow for efficient decision-making in the timelines set by the REACH Regulation. That means that after the draft decision has been notified to the registrant for comments no updates received <u>will normally</u> be taken into account for the adoption of the taken decision*' [emphasis added].

48. The logical interpretation of the wording '*if no reference is made in the registrant's comments […] [the Agency] does not normally take into account dossier updates*' is that, if a reference to a pending dossier update is made in the registrant's comments, that dossier update will be taken into account by the Agency. Practical Guide 12 does not indicate that the registrant should repeat the content of its future dossier update in its comments on the draft decision in order for it to be taken into account by the Agency. There is also no indication in Practical Guide 12 by which date a dossier update mentioned in the comments on a draft decision must be made in order for it to be taken into account in the decision-making procedure.

49. The words '*does not normally*' in Practical Guide 12 can also be interpreted as meaning that there are in fact situations where dossier updates will be taken into account even if there is no mention in the comments on the draft decision that the registrant plans to update its registration dossier.

50. The section of Practical Guide 12 referred to in paragraphs 2 and 47 above contains a footnote referring to the news alert of 28 January 2015. However, since Practical Guide 12 was published after the news alert, the Appellant could assume that Practical Guide 12 expressed the Agency's latest instructions regarding the possibility of dossier updates being taken into account during the decision-making procedure. As part of the principle of legal certainty, registrants should be able to rely on the most recent instruction issued by the Agency being up-to-date and correct.

51. The Agency also explained its new approach to the use of the cut-off point in its cover letter of 14 December 2015 accompanying the draft decision. In the cover letter, the Agency re-states the position expressed in its news alert of 28 January 2015 as follows:

'*[the Agency] does not take into account <u>any</u> dossier updates after the notification of this draft decision under Article 50(1) […]. Any such update will be examined by [the Agency] after the deadline set in the adopted decision has passed*' [emphasis added].

52. As with the news alert of 28 January 2015, and unlike in Practical Guide 12, there is no indication that dossier updates received after the draft decision has been notified to the Appellant may be taken into account. There is no indication that dossier updates mentioned in the comments on the draft decision will be taken into account. There is also no indication that the registrant should repeat the content of any proposed dossier update in its comments on the draft decision.

53. The explanations of the approach to the use of the cut-off point set out in the news alert of 28 January 2015, Practical Guide 12 and the cover letter to the draft decision, were therefore inconsistent and did not allow the Appellant to know without ambiguity its rights and obligations.

54. Furthermore, between July 2015, when Practical Guide 12 was published, and 14 December 2015, when the Appellant received the cover letter to the draft decision, the Appellant was justified in assuming that the rule on the cut-off point for dossier updates set out in Practical Guide 12 applied. Before receiving the draft decision, the Appellant could therefore assume that it would be given the opportunity to update its registration dossier to correct any failings identified by the Agency in its draft decision, at least, if the pending update was mentioned in the comments on the draft decision. The Appellant could also assume that its subsequent dossier update would be taken into account in the decision-making procedure.

55. On 14 December 2015, the Agency individually informed the Appellant for the first time that the Agency would not take into account dossier updates received after the draft decision was notified to the Appellant. However, the draft decision was also notified to the Appellant on 14 December 2015 (see paragraphs 4 and 6 above). Since the Appellant was notified of the deadline for dossier updates to be taken into account on the same day as that deadline expired, it was unable to react to this deadline. Furthermore, as the Appellant could not have been aware of the Agency's strict deadline for dossier updates prior to receiving the letter of 14 December 2015, it was not able to plan for this situation. Even if the Appellant had clearly understood in advance that the cut-off point was the date it received the draft decision, it did not know when it would receive the draft decision. Therefore, it had no way of knowing in advance the date of the cut-off point.

56. The Agency's notification of the cut-off point to the Appellant therefore fails to meet the fundamental requirement of the principle of legal certainty that registrants must be made aware in a timely manner and in a clear and precise way of the applicable rules so that they can plan their actions accordingly.

57. Additionally, the Agency's submissions during these proceedings indicate that the rule on cut-off points set out in its letter of 14 December 2015 does not correspond in all cases to how the Agency treats dossier updates submitted during the compliance check decision-making procedure.

58. At the oral hearing in the present case, the Agency clarified that it does take into account dossier updates submitted within the 30 days granted to registrants to provide comments on the draft decision provided that the update is reflected in the comments on the draft decision. The Agency also stated that, in exceptional circumstances, it would take into account information received during the compliance check decision-making procedure where that information would remove the basis for the decision.

59. However, the Agency's clarifications mentioned in the previous paragraph are inconsistent with the statement in the letter of 14 December 2015 that dossier updates received after the notification of the draft decision will be examined only after the deadline set to provide the information requested in the adopted decision has passed.

60. Furthermore, the Agency stated at the oral hearing that it did in fact examine the Appellant's dossier update of 16 August 2017. However, since the Agency considered that the dossier update of 16 August 2017 did not contain substantial new information that would change the Agency's findings in the Contested Decision, it did not mention that dossier update in the draft of the decision that was discussed at the MSC.

61. By examining the Appellant's dossier update of 16 August 2017, the Agency therefore acted inconsistently with the statement in the letter of 14 December 2015 that dossier updates received after the notification of the draft decision will be examined only after the deadline set to provide the information requested in the adopted decision has passed.

62. The Agency's examination of the Appellant's dossier update of 16 August 2017 is also in direct contradiction with the statement in the cover letter to the Contested Decision that *'[the] decision was adopted without considering any dossier updates submitted after the draft decision was notified to you following the procedure in Article 50(1) […]. Any update submitted after this date concerning the requirement(s) addressed by the enclosed decision will be examined by [the Agency] only after the deadline established in the enclosed decision has passed'.*

63. Furthermore, the conclusion that the dossier update did not contain substantial new information is not assessed or even mentioned in the Contested Decision. As a result, it is not clear that this information was taken into account by the MSCAs or the MSC before the adoption of the Contested Decision. Furthermore, the Appellant was not given the opportunity to comment on the Agency's conclusion that the dossier update of 16 August 2017 did not contain substantial new information. As a result, the Appellant was not placed in a position to make known its views on the Agency's assessment of its dossier update. The Agency's assessment of the Appellant's dossier update was only made known during the present proceedings. There is no record in the documents prepared during the decision-making procedure, or in the Contested Decision itself, of the fact that the Agency did in fact examine the dossier update of 16 August 2017.

64. In view of paragraphs 45 to 63 above, the cut-off point was expressed inconsistently and confusingly by the Agency in the news alert, in Practical Guide 12, in the letter accompanying the draft decision, and during these appeal proceedings. The Agency also acted contrary to its own communications regarding the cut-off point. It was therefore unclear to the Appellant whether, and in what circumstances, a dossier update received after 14 December 2015 would be taken into account. If a dossier update submitted after 14 December 2015 would be taken into account, it was unclear to the Appellant how it should inform the Agency that it intended to submit such an update. If a dossier update submitted after 14 December 2015 would be taken into account, it was unclear to the Appellant how it should provide the information for the dossier update.

65. The Agency therefore breached the requirement for legal certainty. The Agency failed to ensure that the cut-off point applicable in the present case was clearly and precisely communicated to the Appellant. The Appellant could not therefore know unambiguously what its rights and obligations were so that it could take steps accordingly. The Agency also breached the requirement for legal certainty by failing to ensure that the exact cut-

off point applicable in the present case was communicated in a timely manner so that the Appellant could know precisely the time at which the measure came into being and began to have legal effects.

66. The Board of Appeal's finding that the Agency breached the principle of legal certainty is not, for the following reasons, affected by the Agency's argument (see paragraph 38 above) that the Board of Appeal has already confirmed in its decisions in Case A-001-2014, *CINIC Chemicals Europe*, and Case A-017-2014, *BASF SE*, that the Agency may refuse to take into account information received after a cut-off point set by the Agency (Case A-001-2014, *CINIC Chemicals Europe*, Decision of the Board of Appeal of 10 June 2015, and Case A-017-2014, *BASF SE*, Decision of the Board of Appeal of 7 October 2016).

67. In performing its tasks under the REACH Regulation, the Agency is required to take into consideration all the relevant factors and circumstances of the situation the act in question was intended to regulate (see, for example, A-005-2016, *Cheminova A/S*, Decision of the Board of Appeal of 30 January 2018, paragraph 128). The Agency's refusal to take into account dossier updates after the draft decision has been sent to the registrant pursuant to Article 50(1) could lead to a situation where the final decision adopted by the Agency is not based on all relevant factors and circumstances.

68. However, in Case A-001-2014, *CINIC Chemicals Europe*, and Case A-017-2014, *BASF SE*, the Board of Appeal acknowledged that the obligation to take into account all the relevant factors and circumstances of a particular case may, in the circumstances set out in the following paragraph, be limited by the setting of a cut-off point.

69. In Cases A-001-2014 and A-017-2014, the cut-off point for dossier updates set by the Agency was the date on which the draft decision was sent to the MSCAs for their proposals for amendment pursuant to Article 51(1). In those cases, the Board of Appeal found that, for reasons of administrative efficiency, the Agency could apply that particular cut-off point provided that it had mechanisms in place to take into account substantial new information coming to light after that cut-off point. The Board of Appeal therefore acknowledged that the obligation to take into account all the relevant factors and circumstances of a particular case may exceptionally be limited to substantial new information after the draft decision has been sent to the MSCAs for their proposals for amendment.

70. In Cases A-001-2014 and A-017-2014, the Board of Appeal found therefore that after a draft of the decision is sent to the MSCAs it is justifiable that the Agency should only be required to take into account substantial new information in its decision-making. This was for reasons of administrative efficiency which includes, in particular, the need for the MSCAs, the MSC and the Agency to have settled facts at a determined time towards the end of the decision-making procedure. In addition, where the Agency follows the decision-making procedure set out in the REACH Regulation without undue delays, the likelihood of substantial new information coming to light after the draft decision has been sent to the MSCAs is reduced.

71. In the present case, there was more than an 18 month delay between the Appellant commenting on the draft decision and a draft decision being sent to the MSCAs for proposals for amendment. Such a long delay in the decision-making procedure significantly increases the possibility of information coming to light that may affect the final decision.

72. The Board of Appeal has also previously found that the Agency may be required to take into consideration new information that comes to light at any stage during the decision-making procedure set out in Articles 50 and 51. The Board of Appeal has found that, if relevant information comes to light during the decision-making procedure set out in Articles 50 and 51, the Agency may, depending for example on the relevance and importance of the new information, be required to re-start, or repeat certain steps of, the decision-making procedure laid down in Articles 50 to 52. This might be necessary

in some cases to ensure that all the relevant actors are given the opportunity to comment on that information (Case A-023-2015, *Akzo Nobel Chemicals and Others*, Decision of the Board of Appeal of 13 December 2017, paragraph 306).

73. A practice whereby the Agency does not take into account any dossier updates after the notification of the draft decision, without exception, is therefore inconsistent with the Board of Appeal's previous decisions, in particular those in Cases A-001-2014 and A-017-2014.

74. As a minimum, based on the abovementioned decisions of the Board of Appeal, substantial new information in a dossier update must be taken into account even if submitted after a draft of the decision has been sent to the MSCAs.

75. The Board of Appeal's finding that the Agency breached the principle of legal certainty is also not affected by the Agency's argument that the Appellant's registration dossier should have been up-to-date prior to receipt of the draft decision (see paragraph 36 above) for the following reasons.

76. In the present case the Agency, as well as the MSCAs and the MSC, are required to exercise their discretion when deciding whether the registration requirements in question have been satisfied. For example, with regard to the carcinogenicity study, the Agency must assess whether the uses of the Substance result in '*widespread dispersive use*' or '*frequent or long-term human exposure*' (Column 2 of Section 8.9.1. of Annex X). Similarly with regard to the PNDT study, the Agency must assess whether '*appropriate risk management measures are implemented*' (Column 2 of Section 8.7. of Column X). For the EOGRTS, in the form requested in the Contested Decision, the Agency must assess whether '*the substance has uses leading to significant exposure of consumers or professionals taking into account, inter alia, consumer exposure from articles*' (Column 2 of Section 8.7.3. of Annex X).

77. As a result, prior to a compliance check, a registrant may consider that it had satisfied the abovementioned information requirements for registration purposes. From the registrant's perspective there would therefore be no reason to update its dossier. It cannot therefore be assumed that a registrant should be aware that its dossier is missing certain information prior to receiving a draft decision and that it needs to update its dossier. The Agency must assess whether a registration dossier is compliant and, if not, identify in the draft decision the information required in order for the dossier to be compliant.

78. For the same reasons, the Agency's argument that the Appellant should have updated its registration dossier because the Substance was included on CoRAP (see paragraph 37 above) is also rejected.

79. The Board of Appeal's finding that the Agency breached the principle of legal certainty is also not affected by the Agency's argument that it will in any case examine the dossier update after the deadline set in the Contested Decision for the following reasons.

80. Firstly, the Agency stated during the present proceedings that it did in fact examine the dossier update of 16 August 2017 and found that it did not alter its findings in the Contested Decision (see paragraphs 39 and 60 above). Secondly, the information included in the dossier update may be of such a nature that the Agency is later required, pursuant to Article 42(1), to undertake a new decision-making procedure in accordance with Articles 50 and 51. In this situation, the administrative efficiency reasons identified by the Agency for having a cut-off point are diminished. If the Agency considers that the information provided in the dossier update does not affect the need for the Appellant to provide additional information, it would be more efficient to include those reasons in the first compliance check decision adopted under Article 41. This would potentially avoid the need to later undertake an additional decision-making procedure under Article 42(1). This would enable the Agency to obtain the information in question earlier, thereby potentially improving the protection of human health and the environment.

Conclusion on the plea regarding legal certainty

81. As stated in paragraph 65 above, the Agency breached the principle of legal certainty in the present case. The form of order sought by the Appellant (see paragraph 25 above) is therefore upheld in its entirety. The requirements to provide information on a carcinogenicity study and a PNDT study are annulled and the case is remitted to the Agency for further action in relation to these two endpoints. The requirement to provide information on an EOGRTS is annulled in so far as it requires the extension of cohort 1B to include the F2 generation.

82. As the appeal has been upheld in its entirety, it is not necessary to examine the Appellant's other pleas.

Refund of the appeal fee

83. 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 the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee is to be refunded if the appeal is decided in favour of an appellant.

84. As the appeal has been decided in favour of the Appellant, the appeal fee must be refunded.

Effects of the Contested Decision

85. The Contested Decision required the Appellant to submit information on a carcinogenicity study, a PNDT study and an EOGRTS by 17 May 2023. That is five years, six months and seven days from the date of the Contested Decision.

86. The requirement for a carcinogenicity study and a PNDT study have been annulled by the Board of Appeal. The requirement to provide information on an EOGRTS has been annulled in so far as it requires the extension of cohort 1B to include the F2 generation. The Appellant must therefore provide information on the EOGRTS in accordance with Column 1 of Section 8.7.3. of Annex X (test method: EU B.56/OECD TG 443) in rats, oral route.

87. In response to a question from the Board of Appeal, the Agency stated that a period of 24 months would be required to perform the EOGRTS requested in the Contested Decision. The Appellant stated that it would require between 23 and 25 months to update its registration dossier with information on the EOGRTS requested in the Contested Decision. The Parties did not provide any information regarding the amount of time necessary to update a registration dossier with information on an EOGRTS without the extension of cohort 1B to include the F2 generation.

88. The Appellant did not seek the annulment of the requirement to provide information on an EOGRTS in its entirety. However, the Appellant could not be expected to commence the study without certainty as to whether an extension of cohort 1B to include the F2 generation was necessary. In addition, the Contested Decision states that '*the carcinogenicity study shall be conducted before the EOGRTS and the PNDT study. The results from the carcinogenicity study shall be used to consider if further testing for EOGRTS and PNDT is necessary*'. As a result, in the present case, the suspensive effect provided for in Article 91(2) must be considered as applying to the request to provide information on an EOGRTS in its entirety.

89. Having regard to paragraphs 85 to 88 above, the information on the EOGRTS, as modified by this decision, must be submitted within 24 months from the date of notification of the Board of Appeal's decision in the present case.

On those grounds,

THE BOARD OF APPEAL

1. **Annuls the requirements to provide information on a carcinogenicity study and a PNDT study.**
2. **Remits the case to the competent body of the Agency for further action in relation to the carcinogenicity study and the PNDT study.**
3. **Decides that the information on the EOGRTS (Column 1 of Section 8.7.3. of Annex X; test method: EU B.56/OECD TG 443) in rats, oral route, without the extension of cohort 1B to include the F2 generation, must be submitted by 9 April 2021.**
4. **Decides that the appeal fee must be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal