EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

1 August 2016

(Compliance check – Weight of evidence adaptation - Column 2 of Section 8.7 of Annex IX adaptation - Pre-natal developmental toxicity study)

Case number	A-003-2015
Language of the case	English
Appellant	BASF Pigment GmbH, Germany
Contested Decision	CCH-D-0000004057-77-06/F of 26 November 2014 adopted by the European Chemicals Agency (hereinafter 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; hereinafter 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

Summary of the facts

1. On 24 February 2015, the Appellant lodged the present appeal at the Registry of the Board of Appeal against the Contested Decision. The Contested Decision requests the Appellant to submit a pre-natal developmental toxicity (hereinafter 'PNDT') study in rats or rabbits, oral route, following test method EU B.31/OECD 414 (hereinafter the 'PNDT study') for the Appellant's registered substance in order to fulfil the information requirements of Section 8.7.2 of Annex IX to the REACH Regulation (all references to Articles, Recitals and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

Background to the dispute

2. The Appellant registered the substance antimony nickel titanium oxide yellow (CAS No 8007-18-9, EC No 232-353-3) (hereinafter the 'Substance').

3. On 25 April 2013, the Agency initiated a compliance check of the Appellant's registration dossier for the Substance. The registration dossier included an adaptation pursuant to the third indent of Column 2 of Section 8.7 of Annex IX to fulfil the information requirement for the developmental toxicity endpoint, Section 8.7.2 of Annex IX (hereinafter the 'Column 2 adaptation'). A Column 2 adaptation has three cumulative conditions, namely evidence of low toxicological activity, proof from toxicokinetic data that no systemic absorption occurs through the relevant routes of exposure, and evidence that there is no or no significant human exposure.

4. On 29 May 2013, the Agency sent a draft decision to the Appellant (hereinafter the 'Draft Decision'). The Draft Decision rejected the Appellant's claimed Column 2 adaptation on the grounds that the Appellant had failed to show that there was no systemic absorption via relevant routes. The Appellant did not provide any comments on the Draft Decision despite being invited to do so.

5. On 7 August 2013, the Appellant updated its registration dossier including further justification to show that the Substance presented low systemic absorption.

6. On 12 June 2014, the Agency notified the Competent Authorities of the Member States (hereinafter the 'MSCAs') of the Draft Decision and invited them, pursuant to Article 51(1), to submit proposals for amendment within 30 days. One proposal for amendment was subsequently submitted to the Agency.

7. On 18 July 2014, the Agency notified the Appellant of the proposal for amendment and invited it, pursuant to Article 51(5), to provide comments on the proposal for amendment within 30 days. The Appellant did not submit any comments on the proposal for amendment. On 28 July 2014, the Agency referred the Draft Decision to the Member State Committee (hereinafter the 'MSC') pursuant to Article 51(4).

8. On 1 September 2014, the MSC unanimously agreed on the Draft Decision and adopted it as the Contested Decision. The Contested Decision was notified to the Appellant on 26 November 2014.

9. In the Contested Decision, the Agency required the Appellant to submit a PNDT study for the Substance in order to fulfil the standard information requirements of Section 8.7.2 of Annex IX.

10. The Agency inter alia stated in the Contested Decision that the studies submitted by the Appellant in its registration dossier'*[did not provide] the information required by [Section 8.7.2 of Annex IX] because [they lacked], amongst others, sound data on pre- and post- implantation losses, external, soft tissue and skeletal malformations, types and incidences of individual anomalies'.*

11. Concerning the claimed Column 2 adaptation, the Agency stated in the Contested Decision that '*the Appellant [had] in the dossier update still not documented that the cumulative conditions of the adaptation possibility are fulfilled. While [the Appellant] had in the dossier provided some evidence of low toxicity, it had not been shown/documented that that there was "no systemic absorption via relevant routes"'.* The Contested Decision further states that the Appellant had *'sought to demonstrate that there is low systemic absorption. [The Appellant] would have had to demonstrate that there is no systemic absorption'.* The Contested Decision also notes that '*according to information provided by the Appellant, there is systemic absorption of the substance'.* Furthermore, *'there are no data on titanium and nickel bioavailability in the dossier and the modifiers CU0, Cr203, or L120 are not addressed in the available studies'.*

12. Concerning the third cumulative condition of the Column 2 adaptation, the Agency observed that '*the substance is contained in consumer products and in articles handled by consumers'.*

13. The Agency concluded in the Contested Decision that the Appellant had not documented that the three cumulative conditions of a Column 2 adaptation were met. Whilst the Appellant had provided some evidence of low toxicity, it had not documented the lack of absorption by relevant routes or the lack of human exposure. Consequently, the Agency considered that there was an information gap and requested the Appellant to provide information on PNDT pursuant to Section 8.7.2 of Annex IX.

14. The Contested Decision required the Appellant to submit the results of the PNDT study by 3 December 2015.

Procedure before the Board of Appeal

15. On 24 February 2016, the Appellant lodged the present appeal. The Appellant requests the Board of Appeal to annul the Contested Decision and order the Agency to refund the appeal fee.

16. On 18 May 2015, the European Coalition to End Animal Experiments (hereinafter 'ECEAE') applied to intervene in the proceedings in support of the Appellant. On 6 July 2015, the Board of Appeal dismissed ECEAE's application to intervene on the grounds that the application to intervene had been received after the time limit provided for in Article 8(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'.)

17. On 27 April 2015, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded. Following consultation with the Parties, the appeal proceedings were stayed between 17 June 2015 and 1 September 2015 in accordance with Article 25 of the Rules of Procedure.

18. On 21 October 2015, the Appellant lodged observations on the Agency's Defence. On 3 December 2015, the Agency submitted observations on the Appellant's observations on the Defence.

19. On 22 December 2015, the Board of Appeal submitted a list of written questions to the Appellant and the Agency. The Appellant and the Agency responded to the Board's questions on 8 February 2016 and 11 February 2016 respectively.

20. On 3 March 2016, the Parties were notified of the Board of Appeal's decision to close the written procedure.

21. On 8 March 2016 and 17 March 2016 respectively, the Appellant and the Agency informed the Board of Appeal that they did not request a hearing to be held in the present case. On 1 April 2016, the Board of Appeal notified the parties that no hearing would be held.

Reasons

22. In support of its appeal, the Appellant raises, in essence, five pleas in law which may be summarised and broken down as follows.

The first plea alleging that the Contested Decision lacks a legal basis

Arguments of the Appellant

23. In support of its first plea the Appellant argues that it fulfilled the standard information requirement for PNDT pursuant to Section 8.7.2 of Annex IX through a weight of evidence approach as foreseen in Section 1.2 of Annex XI (hereinafter the 'weight of evidence adaptation'). The Appellant argues that it provided in its registration dossier sufficient weight of evidence from several independent sources on the Substance to justify the adaptation. The Appellant concludes that the Contested Decision requiring it to fulfil the standard information requirement for PNDT therefore lacks a legal basis.

24. The Appellant further states that, on 28 January 2013, the Agency conducted a webinar on its website entitled 'How to bring your registration dossier in compliance with REACH – Tips and Hints: Higher Tier Human Health Studies' (hereinafter the 'webinar'). The webinar included slides outlining the possibilities for registrants to claim an adaptation of the information requirement for a PNDT study as required under Section 8.7.2 of Annex IX.

25. The webinar, according to the Appellant, described in particular two possibilities for adaptation from the standard information for the PNDT study namely a Column 2 adaptation and a weight of evidence adaptation. The Appellant adds that the webinar in relation to the weight of evidence adaptation for the PNDT study *'proposed to*

present data for unreactive substances consisting of low absorption and low toxicity to waive [the PNDT study]'. The Appellant argues that it followed the recommendations explained in the webinar. In particular, the Appellant stresses, regarding the no absorption condition of the Column 2 adaptation, that the '*webinar has adopted a more pragmatic approach, requiring the registrant to show "low absorption"'*. The Appellant adds that the cut-off criteria for the classification of mixtures under Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p.1; corrected by OJ L 136, 29.5.2007, p. 3, corrected by OJ L 138, 26.5.2011 p. 66) (hereinafter the 'CLP Regulation') '*has been considered on several occasions to represent the demarcation line between relevant and irrelevant exposure to a substance'.* The Appellant argues that the threshold for classification of mixtures as category 1A reproductive toxicants and the threshold of 0.1% concentration of category 1 or 2 reproductive toxicants in mixtures, on or via lactation requiring a Safety Data Sheet, could '*arguably serve as a suitable approach to define the range of low absorption and that the [Substance] in question conforms to both'.*

Arguments of the Agency

26. The Agency argues that the Appellant is implying that the rate of absorption of the Substance is below the thresholds in the CLP Regulation, for reproductive toxicity, leading to the classification of mixtures or the requirement for a Safety Data Sheet to be provided and this led the Appellant to conclude that the Substance's absorption would be low. The Agency argues however that the Appellant's registration dossier did not contain this argument.

27. The Agency argues further that there is no scientific merit in comparing the concentration of a substance in a mixture that is outside a human body to internal exposure. The Agency adds that the second cumulative condition of the Column 2 adaptation is that no systemic absorption occurs for example when *'plasma/blood levels [are] below [the] detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air*'. The Agency adds that evidence on the Substance lead it to conclude that the Substance could be absorbed and that the cumulative conditions of the Column 2 adaptation were therefore not fulfilled.

28. The Agency further argues that the weight of evidence adaptation proposed by the Appellant in the present case relies on the same arguments as the Column 2 adaptation presented by the Appellant in its registration dossier. The Agency adds that the Appellant's registration dossier did not contain an explicit weight of evidence adaptation and the Agency was therefore not required to assess such an adaptation. The Agency concludes that the Appellant's plea on the lack of legal basis of the Contested Decision must therefore be dismissed.

29. As regards the Appellant's second argument concerning the criteria presented by the Agency in the webinar, the Agency argues that even if the Appellant had presented a weight of evidence adaptation in its dossier it would not have complied with the criteria outlined in the webinar as '*the focus has to be meeting the information requirements for the respective endpoint, e.g. the key parameters need to be covered*'. The Agency notes that the Appellant's dossier did not contain information on '*external, visceral, and skeletal malformations and variations*' constituting key

parameters of a PNDT study, as stated in the Contested Decision (see paragraph 10 above).

Findings of the Board of Appeal

30. The Appellant contends by its first plea that the Contested Decision lacks a legal basis. In this respect, the Board of Appeal notes that the Contested Decision is a decision following a compliance check initiated pursuant to Article 41 and adopted pursuant to Article 51. Consequently a legal basis exists for it. However, the Board of Appeal observes that under this generic plea claiming a lack of legal basis the Appellant argues in essence that it submitted information that satisfies the PNDT endpoint and, in requesting a PNDT study in the Contested Decision, the Agency has not assessed its registration dossier correctly.

31. The Board of Appeal therefore finds that, rather than contending that the Contested Decision lacks a legal basis, the arguments raised by the Appellant under this plea directly concern the assessment performed by the Agency of the Appellant's registration dossier. The Board of Appeal will therefore assess whether the Agency made an error of assessment.

32. When assessing whether the Agency has made an error of assessment, the Board of Appeal must examine whether the Agency has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached (see, Case A-004-2014, *Altair Chimica Spa and others*, Decision of the Board of Appeal of 9 September 2015, paragraph 42; see also by analogy, Case T-71/10, *Xeda International and Pace International v Commission*, EU:T:2012:18, paragraph 71).

33. The Board of Appeal notes in this regard that, in light of the submissions made for the purposes of this appeal, the Appellant has submitted in support of its registration dossier for the PNDT endpoint a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422), an oral 90 day toxicity study supplemented by a 5 day inhalation study with a 60 day post exposure period and several in vitro leaching studies at different pH values, all on the Substance. Drawing from the results of these studies, the Appellant concludes that '*the bioavailability of the relevant ions is extremely low'.* The Appellant argues that this finding fulfils the second condition of the Column 2 adaptation in stating that '*it seemed logical for [the Agency] to read the legal text "no systemic absorption", which is part of [the second condition of the Column 2 adaptation], as meaning "no significant bioavailability"'.* The Appellant adds that *'[w]hile not contesting that no study beyond an OECD 422 screening study exists that examined external, visceral or skeletal malformations, the Appellant submits that it can be expected that no such effects [of developmental or reproductive toxicity] occur in a study up to the limit dose if the bioavailability is negligible. It should be stressed that, apart from the fact that only one of the ions present in the pigment was bioavailable at a very low level, antimony ions are not considered reproductive toxicants. Therefore, it is in the spirit of [the Column 2 adaptation] that bioavailability is viewed as a surrogate to cover key parameters of PNDT studies'.*

34. The Agency indicated in the Contested Decision that the Appellant had not provided sufficient information to show that the conditions of the Column 2 adaptation were met. In its Notice of Appeal, the Appellant argues that its weight of evidence approach was sufficient to satisfy the PNDT endpoint. The Appellant's submissions in the present

appeal also aim to explain how a weight of evidence approach fulfils the cumulative conditions of the Column 2 adaptation.

35. As a preliminary observation the Board of Appeal acknowledges that a Column 2 adaptation and a weight of evidence adaptation serve different purposes. A Column 2 adaptation in essence means that, in light of the properties of the Substance and its uses, a PNDT study would not provide useful information on the PNDT endpoint. A weight of evidence adaptation however means that all relevant information on the PNDT endpoint is already available through existing information and that there is therefore probably nothing to be gained by undertaking a PNDT study. In short, a Column 2 adaptation means that information on the PNDT endpoint is not needed whilst a weight of evidence adaptation means that the information on the PNDT endpoint already exists. The evidence to justify one adaptation is therefore unlikely to support the other.

36. Bearing in mind the different rules for different adaptations and in order to decide whether there was any error committed by the Agency, the Board of Appeal will examine the Agency's assessment of the information contained in the Appellant's dossier following three steps. In a first step, the Board of Appeal will examine whether the Agency is correct in finding that the three cumulative conditions of the Column 2 adaptation are not met. In a second step, the Board of Appeal will consider whether the Agency correctly assessed the approach claimed by the Appellant that it used weight of evidence to fulfil the cumulative conditions of the Column 2 adaptation. And in a third step, the Board of Appeal will analyse whether the Agency made an error of assessment of the Appellant's dossier in light of the general rules for using a weight of evidence adaptation as laid down in Section 1.2 of Annex XI.

(i) The three cumulative conditions of the Column 2 adaptation

37. As regards the three cumulative conditions of the Column 2 adaptation, the Board of Appeal observes that the Column 2 adaptation in question is used to show that information on the PNDT endpoint is not necessary as it would not provide further useful information on that endpoint.

38. The first cumulative condition of the Column 2 adaptation concerns the low toxicological activity of the substance. The Agency indicated in the Contested Decision that the Appellant had provided in its dossier '*some evidence of low toxicity*'. The Board of Appeal considers, for the purposes of this appeal, that the Agency accepted that the first cumulative condition could be met.

39. The second cumulative condition of the Column 2 adaptation concerns the proof from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure. The Agency explained in the Contested Decision that according to information provided by the Appellant '*the substance is bioavailable*'. The Agency based its conclusion on the 90 day toxicity study submitted on the Substance by the Appellant which showed, in the Agency's view, that systemic absorption '*must have occurred and there is even proof of bioavailability'*. The Agency justified this finding with reference to the amounts of antimony detected in the rats' kidneys after three months of administration which were above the limit of detection for this study.

40. In its submissions, the Appellant argues that studies demonstrating the low bioavailability of the ions of the Substance can be used as a surrogate for the no absorption condition of the Column 2 adaptation. The Board of Appeal observes that by this statement the Appellant makes an assumption that the Agency would consider

that evidence of low bioavailability satisfies the 'no absorption' condition of a Column 2 adaptation. However the Board of Appeal observes that the wording of the Column 2 adaptation is clear and prescriptive in this regard. If a surrogate to the 'no absorption' condition, or the possibility to substitute test results showing no absorption by results of low absorption, were possible the legislator would have reflected this in the wording of the Column 2 adaptation. The Board of Appeal considers that the Agency would be breaching the REACH Regulation if it were to follow the interpretation suggested by the Appellant. The argument of the Appellant that the second condition of the Column 2 adaptation can be fulfilled by findings on low absorption or low bioavailability must therefore be rejected.

41. The Appellant also argues that the webinar led it to believe that low absorption could be used as a surrogate for no absorption. The Board of Appeal finds however that in the slides from the webinar the possibility of using low absorption as part of an adaptation approach was only made with reference to a weight of evidence adaptation. In particular, the slide of the webinar that the Appellant uses in support of its argument states that '[w]*eight of evidence according to [Section 1.2 of Annex XI] may be proposed when there is sufficient evidence from several independent sources of information. In the case of an unreactive or inert substance, other potentially useful information might consist of [evidence of low absorption and evidence of low toxicity (acute or sub-acute)]'.* The Appellant has presented no evidence showing that the no absorption condition under a Column 2 adaptation could be met by demonstrating low absorption. This argument in the context of a Column 2 adaptation must therefore be rejected.

42. As regards the Appellant's argument that the cut-off criteria for the classification of mixtures under the CLP Regulation could serve as an approach to define low absorption of the Substance, the Board of Appeal has already found in the preceding two paragraphs that the second condition of a Column 2 adaptation is no absorption rather than low absorption. Therefore, and without prejudice to a Board of Appeal examination of the validity of the Appellant's argument, this argument falls as the CLP thresholds, even if they could be applied, would only demonstrate low absorption rather than no absorption.

43. The Board of Appeal finds that the Agency rejected the Appellant's claim on the second cumulative condition of a Column 2 adaptation on the basis of objective arguments and using information submitted by the Appellant in its registration dossier and during the decision-making process. By basing its conclusions on observable results and contrasting them with the Appellant's claims, it is apparent from the Contested Decision that the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance. The Board of Appeal concludes that the Agency was justified in finding that the second cumulative condition of the Column 2 adaptation was not fulfilled by the Appellant. The Agency therefore did not make an error of assessment.

44. The third cumulative condition of a Column 2 adaptation is that there is no or no significant human exposure to the substance. The Agency states in the Contested Decision that '*the [Substance] is contained in consumer products and in articles handled by consumers'*. The Appellant explains for the purposes of the present appeal that the Substance is embedded in a matrix at consumer level meaning that the substance cannot be inhaled and that the Appellant is not a supplier of consumer articles. The Appellant adds that '*[a]nalytical studies show that migration of the*

substance or analogue substances from synthetic materials is below the limit of detection'.

45. The Board of Appeal observes that the concern of the Agency regarding the use by consumers of products containing the Substance has not been addressed by the Appellant. In this regard, it should be taken into account that pursuant to Article 1(3) the burden of proof is on registrants to demonstrate that the substances they manufacture, place on the market or use are safe. The Board of Appeal notes that the Appellant introduced in the course of these appeal proceedings a new argument in support of its plea which is that '*analytical studies*' show that migration of the substance is below the limit of detection. However, the Appellant did not provide these studies or even the references for them. The Board of Appeal finds therefore that this new and unsubstantiated argument cannot be used to call into question the Agency's assessment in this regard. The Board of Appeal finds that the Appellant did not substantiate its claim that there was no or no significant human exposure to the Substance and that there was therefore an error of assessment on the part of the Agency. The Board of Appeal concludes that the Agency correctly found that the second and third conditions of the Column 2 adaptation were not fulfilled and that there was no error of assessment on the part of the Agency in this regard.

(ii) Weight of evidence used to fulfil the three cumulative conditions of the Column 2 adaptation

46. The Board of Appeal will, as a second step, examine if the Agency correctly assessed the claimed weight of evidence approach with regard to the three conditions of the Column 2 adaptation. The Board of Appeal notes that a weight of evidence approach in this context is used to show that the three individual conditions in the Column 2 adaptation are met.

47. The Appellant alleges that it followed the indications given in the webinar to support its approach. The Board of Appeal notes, firstly, that advice given by the Agency in a webinar does not constitute a binding interpretation of the REACH Regulation. Through the use of webinars, the Agency gives advice to help registrants meet their obligations under the REACH Regulation. In certain situations however communications of the Agency may be considered to give rise to legitimate expectations to third parties. The Board of Appeal observes that, from settled case-law of the Court of Justice, the principle of legitimate expectations is '*open to any individual which an institution, by giving him precise assurances, has led to entertain legitimate expectations. Regardless of the form in which it is communicated, precise, unconditional and consistent information which comes from an authorised and reliable source constitutes such assurance*' (see Case T-36/09*, dm-drogerie markt GmbH & Co. KG* v *OHIM*; EU:T:2011:449, paragraph 108).

48. The Board of Appeal will therefore consider the content of the webinar and what relevance this has to the Appellant's plea. The Board of Appeal notes that, concerning weight of evidence, the webinar reproduces the wording of Section 1.2 of Annex XI and indicates further that '*[i]n the case of an unreactive or inert substance, other potentially useful information might consist of [l]ow absorption and [l]ow toxicity (acute or sub-acute toxicity); [i]nformation of a related substance or from a group on the endpoint'*. One of the slides also states that '*the focus has to be on meeting the information requirements for the respective endpoint, e.g. the key parameters need to be covered'.*

49. The Board of Appeal notes that the webinar describes the existence of two different adaptation mechanisms that may be applicable to the standard information requirement for PNDT. Furthermore, the Board of Appeal finds that it is not apparent from the webinar slides that the Agency gave indications to registrants as to how to employ a weight of evidence approach to satisfy the three cumulative conditions of the Column 2 adaptation. The Board of Appeal also considers that the slides of the webinar do not describe a different standard of review of the adaptation possibilities for the PNDT endpoint to that set out in the REACH Regulation. The Board of Appeal finds, as it has already stated in paragraph 41 above, that the Agency's approach as described in the webinar concerning the low absorption of a substance simply points out that this information is potentially relevant to the justification of a weight of evidence adaptation for the PNDT endpoint. Furthermore, the Agency's position as explained in the webinar does not set out a possibility of fulfilling the second condition of the Column 2 adaptation by showing low absorption of a substance.

50. The Board of Appeal acknowledges that in order for a weight of evidence approach, applied to a Column 2 adaptation, to succeed the Appellant would need to provide information showing by weight of evidence that the three cumulative conditions of the Column 2 adaptation were met. However, the Board of Appeal has already found in paragraph 47 that the second and third condition of the Column 2 adaptation were not fulfilled by the Appellant through the data it provided. In other words, the Agency, regardless of the approach used by the Appellant, has found that the data submitted by the Appellant is not sufficient to satisfy the three conditions in the Column 2 adaptation. The Board of Appeal has already observed that the Agency, in its assessment, examined carefully and impartially, and took into consideration, all relevant information and that the Agency did not make an error of assessment in this regard. The Board of Appeal finds that the argument that the Column 2 adaptation was met through weight of evidence must therefore be rejected.

51. In light of the above, the Board of Appeal finds that the Agency did not make an error of assessment in concluding that the Appellant did not satisfy the three conditions in the Column 2 adaptation through the use of a weight of evidence approach.

(iii) Weight of evidence used to fulfil the PNDT endpoint

52. The Board of Appeal will examine, as a third step, whether the Agency made an error of assessment of the Appellant's dossier in light of the general rules for using a weight of evidence adaptation as laid down in Section 1.2 of Annex XI. The Board of Appeal notes that a weight of evidence approach is used in this context to demonstrate that the testing required to satisfy an endpoint does not appear to be scientifically necessary as other information is already available leading to a conclusion that the substance has or has not a particular dangerous property.

53. The Appellant argues, notwithstanding the requirements of the Column 2 adaptation, that its registration dossier fulfils the information requirement for PNDT through weight of evidence. Pursuant to Section 1.2 of Annex XI setting out the general rules for using a weight of evidence approach for adaptation purposes, '*adequate and reliable documentation should be provided*'. The Board of Appeal has previously decided that '*[i]nclusion in the dossier of [adequate and reliable documentation of the applied adaptation method] is essential to allow the Agency to carry out its role, set out in Article 41(1)(b) of the REACH Regulation, of evaluating whether the 'adaptations of standard information requirements and the related justifications […] comply with the rules governing such adaptations set out in Annexes VII to X and the*

general rules set out in Annex XI' (see Case A-006-2012, *Momentive Specialty Chemicals B.V.*, Decision of the Board of Appeal of 13 February 2013, paragraph 58).

54. In this particular case the Appellant did not explicitly claim a weight of evidence approach in its registration dossier. The Board of Appeal further notes that, in response to its questions asking the Appellant to explain whether the registration dossier contained an explicit proposal for a weight of evidence adaptation, the Appellant reproduced sections of its original registration dossier and in particular a statement on the low ion availability of the Substance. The Board of Appeal observes however that none of the submitted text, in response to the question of the Board of Appeal, explicitly refers to this approach as being part of a weight of evidence adaptation. In this respect, the Board of Appeal has found that '*whilst registrants can expect a certain level of expertise within the Agency, it is not the task of the Agency to develop, or improve, read-across adaptations on their behalf*' (see the decision in *Momentive Specialty Chemicals B.V*, cited in paragraph 55 above, paragraph 60). The Board of Appeal finds that, by analogy, it is not the task of the Agency to develop, justify or improve, a weight of evidence adaptation on a registrant's behalf.

55. The Board of Appeal concludes therefore that a weight of evidence adaptation could not have been assessed by the Agency as it was not explicitly claimed by the Appellant and that the Agency could not have been expected to develop or assess a weight of evidence adaptation of its own motion. The Board of Appeal finds that the Appellant's plea in this regard must therefore be rejected as unfounded.

56. The Board of Appeal recalls, in the interests of completeness, that the Agency correctly identified in the webinar that in order for a weight of evidence adaptation to succeed '*the focus has to be meeting the information requirements for the respective endpoint, e.g. the key parameters need to be covered'*. With this in mind, the Board of the Appeal agrees with the conclusion in the Contested Decision that the Appellant's dossier did not contain *'sound data on pre- and post- implantation losses, external, soft tissue and skeletal malformations, types and incidences of individual anomalies'* which constitute key parameters of a PNDT study. Therefore, even if the Agency had addressed a weight of evidence adaptation in the registration dossier, based on the information available, the conditions for a weight of evidence adaptation for the PNDT endpoint for the Substance would not have been fulfilled.

57. The Appellant's first plea must therefore be rejected.

The second plea alleging that the Agency failed to exercise discretion

Arguments of the Appellant

58. By its second plea, the Appellant claims that the Agency failed to exercise its discretion.

59. The Appellant argues that the Agency did not assess the weight of evidence adaptation claimed by the Appellant thereby failing to exercise its discretion. According to the Appellant, the Contested Decision is solely based on the rejection of the Column 2 adaptation. The Appellant argues in support of this plea that the Agency has the obligation to analyse the data '*with regard to every relevant strategy*'.

Arguments of the Agency

60. The Agency refutes the Appellant's claim that the Agency has a duty to explore all possible adaptations under the REACH Regulation when only one adaptation was explicitly claimed by the Appellant. The Agency further notes that Annexes IX and XI '*both require registrants to clearly state the reasons for any adaptation to the standard information under the appropriate headings in the registration dossier*' and that the Appellant failed to do so.

Findings of the Board of Appeal

61. The Board of Appeal observes that the Appellant argues in essence that the Agency has a duty to explore all possibilities for adaptation to the information requirements based on an assessment of all data included in a registration dossier.

62. The Board of Appeal re-iterates, as it found in paragraph 56 above, that the Agency had no obligation to develop, justify or improve a weight of evidence adaptation on a registrant's behalf. The Board of Appeal finds that the Agency therefore did not fail to exercise its discretion in this regard and that this plea should be dismissed.

The third plea alleging that the Agency did not follow good administrative practice and breached the principle of legitimate expectations

Arguments of the Appellant

63. The Appellant argues that the Agency endorsed, through the contents of the webinar, waiving of the PNDT information requirement through a weight of evidence adaptation.

64. The Appellant further submits that the Agency did not follow good administrative practice in that it acted contrary to its own recommendation as presented in the webinar. Furthermore, the Appellant claims that the Agency did not assess the Appellant's waiving arguments based on weight of evidence and erred in not stating reasons for '*refuting the [weight of evidence] approach'*.

65. The Appellant also claims that the Agency breached the principle of legitimate expectations as the webinar created '*expectations as to how [the Agency] would respond to such [a weight of evidence] approach'*.

Arguments of the Agency

66. The Agency, in response to the Appellant's argument that the webinar breached the Appellant's legitimate expectations, argues that '*the webinar does not suggest that [the Agency] will assess a [weight of evidence adaptation] that has not been argued by the registrant'.* The Agency adds that '*the webinar does not provide advice on how to make a waiver argument under [the Column 2 adaptation]'* and '*does not suggest that the condition for a waiver reading "no systemic absorption" in [the Column 2 adaptation] should be read as "low absorption"'.* The Agency concludes that as the Appellant did not follow this advice it could not have had any legitimate expectations from the webinar that its Column 2 adaptation would be accepted.

67. Concerning the Appellant's plea that the Agency erred in not assessing the Appellant's weight of evidence arguments, the Agency argues that it has undertaken a detailed assessment of the Appellant's Column 2 adaptation argument and that it therefore respected good administrative practice by providing a detailed reasoning as to why the

information requirements for the PNDT endpoint were not met. Furthermore, as the Appellant did not claim a weight of evidence approach in its registration dossier it was not required to assess a weight of evidence approach.

Findings of the Board of Appeal

68. The Board of Appeal finds that the webinar indicated two adaptation possibilities for the PNDT endpoint, namely a Column 2 adaptation and a weight of evidence adaptation. The Board of Appeal, as stated above in paragraph 58, has already found that the Agency acted consistently in the present case with its recommendations in the webinar. That is, the Agency did not err in finding, notwithstanding the fact that a weight of evidence adaptation was not explicitly claimed in the registration dossier, that the key parameters were not met with regard to a weight of evidence adaptation. Furthermore, the Agency did not err in finding, see paragraphs 37 to 47 above, that the conditions in the Column 2 adaptation were not met. The Agency acted consistently with its advice given in the webinar and did not therefore act contrary to good administrative practice.

69. The Board of Appeal has already found that the Agency did not commit an error of assessment in concluding that the conditions of the Column 2 adaptation were not met. The Board of Appeal has also found that, in the absence of an explicit claim that a weight of evidence adaptation was being applied to the PNDT endpoint, the Agency did not err in not assessing whether a weight of evidence adaptation would satisfy the PNDT endpoint. The Appellant's claim with regard to legitimate expectations must therefore be rejected as unfounded.

70. Concerning the Appellant's argument that the Agency erred in not stating reasons for refuting the weight of evidence approach, the Board of Appeal observes that in the absence of a duty from the Agency to explore a weight of evidence adaptation in the Appellant's dossier, as noted in paragraph 56 above, it follows that the Agency was not required to state reasons relating to an assessment that it was not required to perform. The argument of the Appellant must therefore be rejected.

71. The Board of Appeal finds that the Appellant's arguments concerning good administrative practice and legitimate expectations must be rejected. The Appellant's third plea is therefore dismissed.

The fourth plea alleging that the Contested Decision breached Article 25(1) on animal welfare

Arguments of the Appellant

72. The Appellant argues that the Contested Decision breaches Article 25(1) and Recital 47, as it is not necessary to conduct the requested PNDT study, nor is it required, because the registration dossier is compliant with the REACH regulation.

Arguments of the Agency

73. The Agency argues that it is entitled to '*reject an adaptation proposal of the registrant if it does not comply with any of the specific or general adaptation rules of the REACH Regulation'.* The Agency notes that *'[its] role in evaluation is in assessing the quality*

of registration dossiers and deciding about testing regimes on [the] basis of the provisions of the REACH Regulation' and adds that the Agency has shown in the present case that the Appellant had not fulfilled the PNDT information requirement in its registration dossier. The Agency concludes that there is therefore no violation of Article 25(1) or Recital 47.

Findings of the Board of Appeal

74. The Board of Appeal notes that Article 25(1) provides that '*[i]n order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests'.* The Board of Appeal recalls that it has previously found in the context of a read-across proposal under Section 1.5 of Annex XI, that *'[t]he Agency's role in this respect is to evaluate whether the requirements of Section 1.5 of Annex XI have been met. The Board of Appeal considers that Article 25(1) of the REACH Regulation does not impose any additional duties on the Agency when a read-across proposal has been made beyond evaluating the proposal*' (see Case A-001-2012, *Dow Benelux B.V.*, Decision of the Board of Appeal of 19 June 2013, paragraph 116). The Board of Appeal observes that the REACH Regulation itself dictates the information requirements for registration purposes and the conditions under which standard information is not required. In the present case, the Board of Appeal considers that the Agency had no additional duty beyond assessing the Appellant's claimed Column 2 adaptation as proposed in the Appellant's registration dossier. As the Board of Appeal has found that the Agency correctly exercised its discretion with regard to the Column 2 adaptation the Appellant's fourth plea must be rejected.

The fifth plea of the Appellant concerning the IUCLID platform

Arguments of the Appellant

75. The Appellant submits that it did not have the possibility '*to adequately describe a [weight of evidence] approach using studies from different endpoints in the current IUCLID system*'. The Appellant submits that the text of the claimed weight of evidence adaptation was entered as an endpoint summary under Section 7.8 of IUCLID entitled '*toxicity to reproduction*'. In essence, the Appellant submits that it conformed to the criteria laid down in Section 1.2 of Annex XI but that IUCLID prevented it from presenting the evidence from other endpoints to support a weight of evidence adaptation for the PNDT endpoint.

Arguments of the Agency

76. The Agency argues that it is technically possible for the Appellant, using different IUCLID endpoints, to flag one study as a main study and other studies as supportive studies for a weight of evidence adaptation. The Agency adds that the Appellant did not contact the Agency's Helpdesk in order to get assistance and that there was no technical problem preventing the Appellant from presenting a weight of evidence adaptation for the PNDT endpoint using studies on other endpoints.

Findings of the Board of Appeal

77. As the Board of Appeal has already observed in paragraph 56 above, the Appellant's registration dossier did not contain an explicit claim for a weight of evidence adaptation but rather a Column 2 adaptation. The Board of Appeal has already found that the Agency could not therefore be expected to have assessed any other adaptation that was not explicitly claimed. The Board of Appeal adds that if the Appellant did indeed notice structural faults in the IUCLID system that prevented it from presenting a weight of evidence adaptation, it did not flag such a problem nor report it to the Agency before the present appeal and therefore failed to act in a diligent and prudent manner (see Case A-020-2013, *Ullrich Biodiesel GmbH,* Decision of the Board of Appeal of 13 November 2014, paragraph 28).

78. The Board of Appeal therefore rejects the Appellant's fifth plea and the appeal must therefore be dismissed in its entirety.

Refund of the appeal fee

79. 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 decision is rectified in accordance with Article 93(1) or the appeal is decided in favour of an appellant.

80. As the appeal has been dismissed, the appeal fee shall not be refunded.

Effects of the Contested Decision

81. According to Article 91(2), an appeal before the Board of Appeal shall have suspensive effect.

82. The part of the Contested Decision challenged in the present proceedings, and upheld by the Board of Appeal, required the registrant, now the Appellant, to submit the required information by 3 December 2015, which is 12 months and 7 days from the date of the adoption of the Contested Decision. The Board of Appeal considers however that, because of the duration of the present appeal proceedings, the deadline set in the Contested Decision should be interpreted, in light of the principle of suspensive effect laid down in Article 91(2) as if it referred to 12 months and 7 days from the date of notification of the final decision of the Board of Appeal.

83. Consequently, the Appellant shall submit the information required in the Contested Decision within 12 months and 7 days from the date of notification of the Board of Appeal's Decision in the present case.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information required by the Contested Decision shall be submitted by 8 August 2017.**
3. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal