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-014-2014
Language of the case	English
Appellant	BASF Pigment GmbH, Germany
Contested Decision	CCH-D-0000005112-88-0 of 16 September 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 dispute

1. On 11 December 2014, 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. On 24 May 2013, the Agency notified to the Appellant a draft decision (hereinafter the 'Draft Decision') following a compliance check of its registration dossier for the substance chrome antimony titanium buff rutile (CAS No 68186-90-3, EC No 269-052-1) also known as C.I. Pigment Brown 24 (hereinafter the 'Substance') pursuant to Article 41(1). In the Draft 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.

3. The Agency noted in the Draft Decision that the information provided by the Appellant in its registration dossier to meet the standard information requirements for the PNDT endpoint, Section 8.7.2 of Annex IX, was obtained from a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) on a different but analogous substance, antimony nickel titanium oxide yellow also known as C.I. Pigment Yellow 53 (hereinafter the 'read-across substance'). The Agency stated in the Draft Decision that these studies *'[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'.* The Draft Decision also stated that *'[the Appellant had] proposed to adapt the information requirement of prenatal developmental toxicity [by application of the adaptation in the third indent of Column 2 of Section 8.7 of Annex IX]*'. The Agency concluded as regards this proposal that *'[the Appellant had] however not documented that the cumulative conditions of that adaptation possibility are fulfilled for the registered substance'*.

4. On 20 June 2013, the Appellant submitted comments on the Draft Decision. In its comments, the Appellant further justified how it met the standard information requirement for PNDT, Section 8.7.2 of Annex IX, by application of the adaptation in the third indent of Column 2 of Section 8.7 of Annex IX (hereinafter the 'Column 2 adaptation').

5. The Appellant updated its registration dossier on 8 July 2013. In the update, the Appellant, according to the Contested Decision, included further justification of its Column 2 adaptation.

6. The Agency revised the Draft Decision (hereinafter the 'revised Draft Decision') and rejected the Appellant's proposed Column 2 adaptation on the basis that it had not

documented that the cumulative conditions of the Column 2 adaptation were met, 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. The Agency argued that while the Appellant had provided some evidence of low toxicity, it had documented neither the lack of absorption by relevant routes nor 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.

7. On 12 June 2014, the Agency notified the revised Draft Decision to the competent authorities of the Member States (hereinafter the 'MSCAs') in accordance with the procedure laid down in Article 51(1). As the Agency received no proposals for amendment from the Member States to the revised Draft Decision it was adopted as the Contested Decision pursuant to Article 51(3) and notified to the Appellant on 16 September 2014.

8. The Contested Decision required the Appellant to submit the results of a PNDT study by 23 September 2015.

Procedure before the Board of Appeal

9. On 11 December 2014, the Appellant lodged the present appeal. The Appellant requested the Board of Appeal to annul the Contested Decision and order the Agency to refund the appeal fee.

10. On 10 February 2015, PETA International Science Consortium Ltd (hereinafter 'PISC') applied to intervene in the proceedings in support of the Appellant. On 11 March 2015, the Board of Appeal granted PISC's application to intervene. On 14 May 2015, PISC informed the Registry of the Board of Appeal that it no longer wished to intervene in the case. On 22 May 2015, the Board of Appeal decided that PISC would no longer be considered to be an intervener in these proceedings.

11. On 16 February 2015, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded. On 9 April 2015, the Appellant lodged observations on the Agency's Defence.

12. Following consultation with the Parties, the appeal proceedings were stayed between 17 June 2015 and 1 September 2015 in accordance with Article 25 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').

13. On 3 December 2015, after the case resumed, the Agency submitted observations on the Appellant's observations on the Defence.

14. 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.

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

16. 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 31 March 2016, the Board of Appeal notified the parties that no hearing would be held.

Reasons

17. In support of its appeal, the Appellant raises, in essence, six 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

18. 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 adaptation 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 evidence from several independent sources on the read-across substance as well as on the Substance itself 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.

19. 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.

20. The webinar, according to the Appellant, described in particular two possibilities for adaptation from the standard information for the PNDT study; a Column 2 adaptation and a weight of evidence adaptation. The Appellant argues that it followed the recommendations explained in the webinar.

Arguments of the Agency

21. The Agency responds 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, its comments of 20 June 2013 to the Draft Decision, and the registration update of 8 July 2013. The Agency adds that the Appellant '*did not attempt to justify his adaptation as [weight of evidence] in the dossier or his comments to the [Draft Decision]*'. The Agency concludes that the Appellant '*relabelled'* for the purposes of the present appeal the Column 2 adaptation as a weight of evidence adaptation and that the Appellant's dossier '*did not contain any [weight of evidence] adaptation in terms of Annex XI, Section 1.2 of the REACH Regulation that [the Agency] should have assessed'.*

22. The Agency also states that the Appellant's registration dossier, after its update of 8 July 2013 which was made by the Appellant before the Contested Decision was issued, did not comply with the cumulative conditions of the Column 2 adaptation that was claimed by the Appellant at that time.

23. In particular, the Agency refers to the statement of reasons in the Contested Decision. The Agency states that the Appellant had not documented how the three cumulative

conditions of a Column 2 adaptation were fulfilled because, while the Appellant had provided some evidence of low toxicity, the information provided showed that the substance was bioavailable and that it was contained in consumer products and in articles handled by consumers.

24. 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.

Findings of the Board of Appeal

25. 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.

26. 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.

27. 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).

28. 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, several studies on the read-across substance, a 90 day repeated dose study, a 5 day inhalation study with a 3 months post-exposure period and a combined 28 day reproductive toxicity screening study. The Appellant also refers in its submissions to a reproductive toxicity screening study performed on the Substance. The Appellant further submitted in its comments, made on 20 June 2013 on the Draft Decision, a table showing the antimony content in rats' livers and kidneys after treatment with nickel rutile yellow and chrome rutile yellow. The Appellant states in its comments that the results shown in this table, which apply to the category of rutile pigments that the Substance and the read-across Substance belong to, prompted it to '*conclude that the low bioavailability of metal ions is a characteristics of rutile pigments'.*

29. The Board of Appeal notes that, according to the Draft Decision, several key parameters for the PNDT endpoint were not met by the information provided in the Appellant's registration dossier, hence the request for a PNDT study. The Agency also indicated in the Draft Decision that the Appellant had not provided sufficient information to show that the conditions of the Column 2 adaptation were met. In its comments to the Draft Decision, and subsequent update of its registration dossier, the Appellant further justified its Column 2 adaptation to satisfy the PNDT endpoint. 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 explain how a weight of evidence approach fulfils the cumulative conditions of the Column 2 adaptation.

30. 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.

31. Bearing in mind the different rules for adaptation and in order to decide whether there was any error committed by the Agency, the Board of Appeal shall 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

32. 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.

33. 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.

34. 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 on the read across substance which showed, in the Agency's view, that systemic absorption '*must have occurred'*. 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. While the Appellant in its comments to the Draft Decision alleged that '*bioavailability of these substances is very low'*, the Agency considered that as the doses were lower in the 90 day study submitted by the Appellant in comparison with the requested PDNT study, '*higher antimony levels [in the rats' kidneys] may be expected at higher doses than those in the submitted study'*.

35. The Board of Appeal finds that the Agency rejected the Appellant's claim that the second cumulative condition is met on the basis of objective arguments and on the basis of the 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 therefore finds that the Agency was justified in finding that the second cumulative condition of a Column 2 adaptation was not fulfilled by the Appellant and that the Agency did not make an error of assessment.

36. The third cumulative condition of a Column 2 adaptation is that there is no or no significant human exposure to the substance. In this respect, the Appellant claimed in its comments to the Draft Decision that '*exposure to the pigment is only relevant to the worker because uptake of the pigment via routes other than inhalation is not possible following formulation into a matrix'.* The Appellant added that the exposure criterion is '*irrelevant*' as leaching and in vivo studies have led European Member States Competent Authorities to exclude the pigment from classification 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'). 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.

37. The Board of Appeal observes that during these proceedings the arguments of the Appellant to support the third condition of no or no significant human exposure are based on the possible inhalation of the Substance only by workers, on the fact that the substance is not marketed to consumers, and on the lack of classification of the Substance under the CLP Regulation. The Appellant made the same arguments about consumer exposure in its comments to the Draft Decision and in its updated registration dossier.

38. 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 in the original registration dossier or in the dossier update of 8 July 2013 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

39. 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.

40. 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*; ECLI:EU:T:2011:449, paragraph 108).

41. 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'.*

42. 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.

43. 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 38 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.

44. 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

45. 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.

46. 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).

47. In this particular case the Appellant did not explicitly claim a weight of evidence approach in its original registration dossier, in its comments of 20 June 2013 or its update of 8 July 2013. The Board of Appeal further notes that, in response to questions from the Board of Appeal asking the Appellant to explain why it had not claimed a weight of evidence adaptation earlier in the process, the Appellant answered that it considered the arguments present in the data it had already submitted in its registration dossier would be '*powerful enough to show that the study required by [the Agency] is scientifically not justified'.* The Appellant added that '*the bulk of the comments do not reference a singular legal provision, but instead present the scientific facts at the heart of the matter in a clear and concise way'.* In other words, the Appellant chose not to explicitly claim a weight of evidence adaptation but rather

considered that the data it submitted would be sufficient in its own right for the Agency to reach a conclusion as to whether any adaptations applied. 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 46 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.

48. 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.

49. 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 information on '*external, visceral, and skeletal malformations and variations*' which constitute key parameters of a PNDT study. Therefore, even if the Agency had addressed a weight of evidence adaptation, based on the information available in the registration dossier, the conditions for a weight of evidence adaptation for the PNDT endpoint for the Substance would not have been fulfilled.

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

The second plea alleging that the Agency failed to exercise discretion

Arguments of the Appellant

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

52. 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

53. 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

54. 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.

55. The Board of Appeal re-iterates, as it found in paragraph 47 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 did not fail to exercise its discretion in this regard and that this plea should therefore 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

56. 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.

57. 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'*.

58. 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

59. The Agency, in response to the Appellant's argument that the Agency, through the webinar, created legitimate expectations that were subsequently not met, argues that '*the Appellant could not have legitimately expected that an adaptation that does not address the key parameters of a PNDT study, as was the present case, would be accepted'.* The Agency also argues that the webinar, as available on the Agency's website, is covered by a general disclaimer posted on the Agency's website which states that *'the website information is of a general nature only and is not intended to address the specific circumstance of any particular individual or entity'*. The Agency concludes that the webinar offers only general advice to registrants and that it cannot serve as an exact source of information for registrants as to what should be included in a justification for an adaptation of information requirements under the REACH Regulation.

60. 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.

61. The Agency also refutes the argument that it had to state reasons for not exploring adaptations not explicitly claimed. The Agency argues, citing a previous decision of the Board of Appeal, that its duty to provide reasons extends only to the measure contained in a decision and adversely affecting its addressee (see Case A-001-2012, *Dow Benelux B.V.,* Decision of the Board of Appeal of 19 June 2013, paragraph 94). As

the Appellant only claimed a Column 2 adaptation in its registration dossier the Agency considers that it only has a duty to provide a reason for rejecting that adaptation. The Agency further concludes that it did not have to state reasons in the Contested Decision as to why it did not address a weight of evidence adaptation which was notexplicitly claimed by the Appellant

Findings of the Board of Appeal

62. 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 has already found in paragraph 49 above that the Agency acted consistently with its recommendations in the webinar. That is, the Agency did not err in finding, for example, 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 33 to 38 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.

63. The Board of Appeal has 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.

64. 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 47 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.

65. 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

66. 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

67. 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 or Recital 47.

Findings of the Board of Appeal

68. 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 Column 2 adaptation as proposed in the Appellant's comments on the Draft Decision and registration update. 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 on the right to be heard

Arguments of the Appellant

69. In its fifth plea, the Appellant alleges that its right to be heard was infringed. The Appellant argues that the paragraph in the Contested Decision concerning human exposure was not included in the Draft Decision and it therefore did not have the opportunity to comment on it.

Arguments of the Agency

70. The Agency argues that the dossier evaluation procedure, pursuant to Article 51(3), does not grant a right to be heard to registrants between the time a draft decision is submitted to the MSCAs and the time the final decision is adopted by the Agency. The Agency adds that in the present case the MSCAs did not have any proposals for amendment and that the revised Draft Decision was therefore adopted without the involvement of the Member State Committee as foreseen by the same article. The Agency also points out that the decision-making process could become never-ending if it was compelled to seek the observations of the registrant every time a change was

made, take every subsequent comment from registrants into account and respond to such comments.

Findings of the Board of Appeal

71. In order to assess this plea, it is necessary to recall the timeline of events in the present case. In the Draft Decision, issued on 24 May 2013, the Agency reminded the Appellant of the three cumulative conditions of the the Column 2 adaptation, the third of which concerns the human exposure to the Substance. The Appellant submitted comments to the Agency on the Draft Decision on 20 June 2013 and updated its dossier on 8 July 2013 including further justifications as to how the three cumulative conditions of the Column 2 adaptation were fulfilled. The Agency adressed these justifications in the Contested Decision.

72. The third criterion of the Column 2 adaptation is that '*there is no or no significant human exposure*'. Consequently, the Agency was under an obligation to address this criterion in its assessment of the Appellant's updated dossier and the Column 2 adaptation therein. The Board of Appeal recalls that the General Court has held that the right to be heard '*must be construed as meaning that it guarantees that the parties will not be confronted with a completely unexpected judicial decision*' (see Case T-133/08, *Ralf Schräder* v *Community Plant Variety Office*, ECLI:EU:T:2012:430 paragraph 181). In the present case the Appellant should clearly have anticipated that the degree of human exposure, the third condition of a Column 2 adaptation, would be assessed by the Agency. The fact that the Agency addressed this criterion in the Contested Decision cannot therefore have resulted in a '*completely unexpected judicial decision*'.

73. The Board of Appeal finds that the Appellant's right to be heard was respected and the fifth plea should therefore be rejected.

The sixth plea of the Appellant concerning the IUCLID platform

Arguments of the Appellant

74. 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

75. 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

76. The Board of Appeal observes that the Appellant, in its answers to the questions of the Board of Appeal as to which part of the Appellant's registration dossier contained an explicit proposal for a weight of evidence adaptation, answered that *'[t]he plain text of the [weight of evidence] approach entered into the IUCLID endpoint summary of 7.8 "toxicity to reproduction" is virtually identical to the Appellant's comments of 20 June 2013 on the Agency's Draft Decision, submitted as Annex I to the Notice of Appeal'.* As the Board of Appeal has already observed in paragraph 47 above, the Appellant's comments on the Draft Decision and update to its registration dossier do not contain an explicit proposal for a weight of evidence adaptation but were used to further justify the Appellant's claimed Column 2 adaptation. The Board of Appeal has already found that the Agency could not be expected to assess an adaptation if it was not explicitly claimed. 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).

77. The Appellant's sixth plea is rejected and the present appeal must therefore be dismissed in its entirety.

Refund of the appeal fee

78. 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.

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

Effects of the Contested Decision

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

81. The part of the Contested Decision challenged in the present proceedings, and upheld by the Board of Appeal, required the Appellant to submit the required information by 23 September 2015, which is 12 months and 7 days from the date of 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.

82. 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