EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

12 December 2017

(Testing proposal – Testing on vertebrate animals – Substance registered exclusively for use as an ingredient in cosmetic products – Relationship between the REACH Regulation and the Cosmetics Regulation – Duty to state reasons)

Case number	A-013-2016
Language of the case	English
Appellant	BASF Personal Care and Nutrition GmbH, Germany
Representative	Kristian Fischer SZA Schilling, Zutt & Anschütz Rechtsanwalts AG, Germany
Interveners	PETA International Science Consortium Ltd. (PISC), United Kingdom The European Coalition to End Animal Experiments (ECEAE), United Kingdom
Contested Decision	TPE-D-2114344602-56-01/F of 21 September 2016 adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 40 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. The Appellant is a registrant of the substance reaction mass of sodium hydrogen N-(1-oxooctadecyl)-L-glutamate and stearic acid (EC No 939-201-1; the 'Substance').

2. The Appellant registered the Substance, exclusively for use as an ingredient in cosmetic products, in the registration tonnage band of 100 to 1000 tonnes per year.

3. The Appellant's registration dossier included a testing proposal for a pre-natal developmental toxicity ('PNDT') study, which is a standard information requirement under Section 8.7.2. of Annex IX to the REACH Regulation.

4. In its testing proposal, the Appellant, instead of proposing a test on its own Substance, proposed a read-across adaptation based on data derived from a PNDT study on an analogous substance (L-Glutamic acid, N-coco acyl derivs., disodium salts; EC No 269-085-1).

5. On 15 October 2015, the Agency notified a draft decision on the testing proposal to the Appellant for comments. The draft decision proposed rejecting the Appellant's read-across adaptation and requiring the PNDT study to be conducted on the Substance.

6. On 30 October 2015, the Agency and the Appellant discussed certain aspects of the draft decision in a telephone conference. In particular, the Appellant expressed its concern that the Substance is registered exclusively for use as an ingredient in cosmetic products and performing a test on the Substance using vertebrate animals may lead to a marketing ban under Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 342, 22.12.2009, p. 59; the 'Cosmetics Regulation').

7. On 17 November 2015, the Appellant submitted comments on the draft decision. The Appellant stated, amongst other things, that '*[the Substance] is solely used as [a] cosmetic ingredient*' and '*there is still uncertainty with regard to the marketing ban laid down in the Cosmetics Regulation*'.

8. The Agency amended the draft decision in light of the comments and information provided by the Appellant in its updated registration dossier.

9. On 21 July 2016, the Agency notified the amended draft decision to the competent authorities of the Member States. No proposals for amendment were submitted by the competent authorities of the Member States.

10. On 21 September 2016, the Agency adopted the Contested Decision in accordance with Article 51(3) of the REACH Regulation.

11. The Contested Decision states amongst other things:

    '*Based on Article 40 of [the REACH Regulation], [the Agency] has taken the following decision.*

    You are requested to perform the following test:

    [PNDT] study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route using the registered substance;

    while your originally proposed test for [PNDT] study (EU B.31./OECD TG 414) oral route, using the analogue substance L-Glutamic acid, N-coco acyl derivs., disodium salts (CAS Nr 68187-30-4) is rejected.

    […]

You are required to submit the requested information in an updated registration dossier by 28 September 2017. You shall also update the chemical safety report, where relevant.'

Procedure before the Board of Appeal

12. On 16 December 2016, the Appellant filed this appeal.
13. On 16 February 2017, the Agency filed its Defence.
14. On 26 April 2017, the Appellant filed observations on the Defence and responded to questions from the Board of Appeal.
15. On 3 May 2017, PISC and ECEAE were granted leave to intervene in this case in support of the Appellant.
16. On 3 July 2017, PISC and ECEAE filed their respective statements in intervention.
17. On 7 July 2017, the Agency filed observations on the Appellant's observations on the Defence and responded to questions from the Board of Appeal.
18. On 22 August 2017, the Appellant and the Agency filed their respective observations on the statements in intervention.
19. On 29 September 2017, a hearing was held at the Appellant's request. At the hearing, the Parties and the Interveners made oral submissions and answered questions from the Board of Appeal.

Form of order sought

20. The Appellant, supported by PISC and ECEAE, requests the Board of Appeal to:
    - annul the Contested Decision,
    - remit the case to the competent body of the Agency for re-evaluation, and
    - order the refund the appeal fee.
21. Should the appeal be dismissed, the Appellant requests a reasonable extension of the deadline to submit the information required by the Contested Decision.
22. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

23. The Appellant raises the following pleas in law against the Contested Decision:
    - a breach of Articles 13 and 25 as well as Section 1.5. of Annex XI to the REACH Regulation, in conjunction with the principle of proportionality;
    - an error of assessment and a breach of the duty to state reasons; and
    - a breach of the principle of good administration.
24. The Board of Appeal will first examine the second part of the second plea, alleging a breach of the duty to state reasons.

The second part of the second plea in law, alleging a breach of the duty to state reasons

Arguments of the Appellant and the Interveners

25. Under Article 18(1)(b) of the Cosmetics Regulation, the placing on the market of cosmetic products is prohibited if they contain ingredients tested on animals '*in order to meet the requirements*' of that Regulation.

26. According to the Appellant, PISC and ECEAE, this provision means that if the Substance were tested on vertebrate animals as a result of the Contested Decision, any cosmetic products containing the Substance could no longer be placed on the market. This concern was repeatedly expressed by the Appellant during the decision-making procedure. The Appellant and the Interveners argue that the Contested Decision should have addressed the fact that the Substance is registered by the Appellant exclusively for use as an ingredient in cosmetic products and the implications of the Contested Decision as a result.

Arguments of the Agency

27. According to the Agency, Article 2(4)(b) of the REACH Regulation provides that the REACH Regulation applies without prejudice to the Cosmetics Regulation.

28. According to the Agency, this means that registrants of a substance registered for use as an ingredient in cosmetic products '*may not perform*' tests on animals under the REACH Regulation unless the substance also has non-cosmetic uses or there is potential worker exposure to that substance. This interpretation is set out in a factsheet published on the Agency's website entitled '*Interface between REACH and Cosmetics regulations*' (ECHA-14-FS-04-EN; the 'factsheet').

29. The Agency also argues that this interpretation is supported by an answer to a parliamentary question given by Commissioner Bieńkowska on behalf of the Commission on 20 February 2017 (E-008614/2016). The Commissioner stated that '*Article 18(1) of the [Cosmetics Regulation] should be interpreted as meaning that animal tests on ingredients of cosmetic products performed in the Union to comply with other Union legislation (e.g. REACH) should not be regarded as having been performed in order to meet the requirements of the Cosmetics Regulation*' and therefore does not lead to a marketing ban.

30. According to the Agency, the Appellant's registration dossier shows that there is potential worker exposure to the Substance. Consequently, the fact that the Substance is registered exclusively for use as an ingredient in cosmetic products is not relevant to the Contested Decision. The exclusive use of the Substance in cosmetic products cannot be a reason for failing to meet the information requirements under the REACH Regulation because workers may also be exposed to it. The Agency therefore did not need to address the relationship between the REACH Regulation and the Cosmetics Regulation in the Contested Decision.

31. Moreover, the Agency argues that it is not competent to interpret the Cosmetics Regulation. In particular, it is not competent to determine whether Article 18(1)(b) of the Cosmetics Regulation leads to a marketing ban for substances tested on animals under the REACH Regulation. This view is supported by the order of the President of the General Court of 13 July 2017 in Case T-125/17 R, *BASF Grenzach* v *ECHA*, EU:T:2017:496, and by the decision of the European Ombudsman of 21 July 2017 in Case 1130/2016/JAS.

32. The Agency states that, in any event, the Appellant was informed about the factsheet and other relevant information publicly available on the Agency's website in the

telephone conference on 30 October 2015. The Appellant therefore knew the reasons underlying the Contested Decision as regards the relationship between the REACH Regulation and the Cosmetics Regulation. It is not the duty of the Agency to assess the implications one of its decisions may have under regulatory frameworks for which it has no specific competence, such as the Cosmetics Regulation.

Findings of the Board of Appeal

33. The Contested Decision is silent on the relationship between the REACH Regulation and the Cosmetics Regulation. It also does not mention the use of the Substance as an ingredient in cosmetic products or potential worker exposure.

34. The Board of Appeal will examine whether these omissions constitute a breach of the duty to state reasons.

- *Requirements of the duty to state reasons*

35. Pursuant to Article 130 of the REACH Regulation and the second paragraph of Article 296 of the Treaty on the Functioning of the European Union, the Agency must state the reasons for any decision it takes.

36. The statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the European Union judicature to exercise its power of review (see judgment of 21 December 2016, C*lub Hotel Loutraki and Others* v *Commission*, C-131/15 P, EU:C:2016:989, paragraph 46).

37. However, whether a statement of reasons is adequate depends on all the circumstances of a case, in particular, the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations (see judgment of 10 March 2016, *HeidelbergCement* v *Commission*, C-247/14 P, EU:C:2016:149, paragraph 16 and the case-law cited). In certain circumstances therefore a more detailed statement of reasons may be required.

- *Whether the relationship between the REACH Regulation and the Cosmetics Regulation is relevant to the Contested Decision*

38. Article 18(1)(b) of the Cosmetics Regulation provides for a marketing ban for cosmetic products containing ingredients which have been tested on animals '*in order to meet the requirements*' of that Regulation.

39. Section 8.7.2. of Annex IX to the REACH Regulation requires registrants in the Appellant's registration tonnage band to perform a PNDT study, which is a vertebrate animal test, unless an adaptation applies.

40. Article 2(4)(b) of the REACH Regulation concerns the application of the animal testing obligations under that Regulation as regards substances used as ingredients in cosmetic products. It states:

'*This Regulation shall apply without prejudice to [Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169–200; the 'Cosmetic Products Directive'] as regards testing involving vertebrate animals within the scope of that Directive*'.

41. Recital 13 to the REACH Regulation states:

'This Regulation should apply without prejudice to the prohibitions and restrictions laid down in [the Cosmetic Products Directive] in so far as substances are used and marketed as cosmetic ingredients and are within the scope of this Regulation. A phase-out of testing on vertebrate animals for the purpose of protecting human health as specified in [the Cosmetic Products Directive] should take place with regard to the uses of those substances in cosmetics.'

42. The Cosmetic Products Directive was repealed and replaced by the Cosmetics Regulation. According to the second paragraph of Article 38 of the Cosmetics Regulation, '*[r]eferences to the repealed Directive shall be understood as references to this Regulation*'.

43. Article 2(4)(b) and Recital 13 of the REACH Regulation must therefore be read as meaning that the REACH Regulation applies without prejudice to the prohibitions and restrictions laid down in the Cosmetics Regulation as regards testing involving animals.

44. This means that there are several possible interpretations of the relationship between the animal testing obligations under the REACH Regulation and the marketing ban under Article 18(1)(b) of the Cosmetics Regulation. Depending on which interpretation is followed, the Agency must or must not require registrants of substances used as ingredients in cosmetic products to perform animal tests.

45. In the present case, the Appellant registered the Substance and stated that it is used exclusively as an ingredient in cosmetic products. The Agency rejected a read-across adaptation proposed by the Appellant and required it to perform a PNDT study, which is a test involving vertebrate animals, on the Substance.

46. The relationship between the REACH Regulation and the Cosmetics Regulation and its interpretation are therefore clearly relevant to the Contested Decision.

- *Whether the Agency should have explained the relationship between the REACH Regulation and the Cosmetics Regulation*

47. The Agency is not competent to apply or implement Article 18(1)(b) of the Cosmetics Regulation. It is also not competent to give a binding interpretation of this provision.

48. However, there are numerous references in the REACH Regulation to the Cosmetic Products Directive (now the Cosmetics Regulation). These include in Articles 2(4)(b), 2(6)(b), 14(5)(b), 56(5)(a) and 67(2) of the REACH Regulation.

49. These references show that the Agency cannot apply the REACH Regulation without having regard to the Cosmetics Regulation.

50. In particular, Article 2(4)(b) of the REACH Regulation sets out the application of vertebrate animal testing obligations under that Regulation for substances used as ingredients in cosmetic products. When interpreting and applying this provision, the Agency must consider, amongst other things, the meaning of Article 18(1)(b) of the Cosmetics Regulation.

51. The Agency must therefore be able to take a position on the interpretation of Article 18(1)(b) of the Cosmetics Regulation insofar as this is necessary to interpret and apply the REACH Regulation.

52. Indeed, the Agency has already taken a position on the interpretation of the relationship between the REACH Regulation and the Cosmetics Regulation. The factsheet, which was published in the Agency's name and on the Agency's website, states:

'*[T]he Cosmetics Regulation does not restrict testing under [the REACH Regulation], if:*

- *this testing is required for environmental endpoints; or*

- *the substance is also registered for non-cosmetic uses.*

Even if a substance is registered exclusively for cosmetic use, the animal testing requirements continue to apply to tests needed to assess the risks from exposure to workers in the Chemical Safety Assessment.'

53. The Board of Appeal therefore rejects the Agency's argument that it is not required to provide its interpretation of the relationship between the REACH Regulation and the Cosmetics Regulation because it is not competent to apply or implement the latter.

54. Moreover, both Regulations have similar objectives and may, as in the present case, apply to the same substance. When interpreting and applying the REACH Regulation account must be taken of related acts such as the Cosmetics Regulation (see, to this effect, judgment of 28 June 2012, *Commission* v *Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraphs 108 to 110).

55. In the present case, an interpretation of Article 2(4)(b) of the REACH Regulation applied in isolation and ignoring Article 18(1)(b) of the Cosmetics Regulation could lead to a situation in which the Agency requires an animal test to be performed under the REACH Regulation even though this could lead to a marketing ban under the Cosmetics Regulation.

56. Furthermore, if the interpretation outlined in the previous paragraph applies, registrants could be obliged to cease marketing substances for use in cosmetic ingredients after complying with an Agency decision requiring animal testing. In these circumstances, the testing would have served no purpose, the costs generated would have been unnecessary and animals sacrificed unnecessarily. This would not be consistent with the case-law cited in paragraph 54 above.

57. Moreover, if the Agency fails to consider Article 18(1)(b) of the Cosmetics Regulation when applying the REACH Regulation and to explain the relationship between the two Regulations, it places registrants of substances used as ingredients in cosmetic products in a position of legal uncertainty.

58. The Board of Appeal therefore rejects the Agency's argument that the Agency has no duty to assess the implications the Contested Decision may have for the Appellant under the Cosmetics Regulation.

59. Finally, it is clear from paragraphs 43 and 44 of the order of the President of the General Court of 13 July 2017 in Case T-125/17 R, *BASF Grenzach* v *ECHA*, EU:T:2017:496, that the President of the General Court has not ruled on the relationship between the REACH Regulation and the Cosmetics Regulation.

60. It is equally clear from paragraphs 43 and 44 of the decision of the European Ombudsman of 21 July 2017 in Case 1130/2016/JAS that the Agency may issue guidance on how the REACH Regulation applies to substances that fall within the scope of both the REACH Regulation and the Cosmetics Regulation.

61. The Board of Appeal therefore rejects the Agency's argument that the order of the President of the General Court and the decision of the European Ombudsman support the position that the Agency has no obligation to take the Cosmetics Regulation into account when applying the REACH Regulation.

62. In any event, even if the Agency had no competence to examine and interpret the Cosmetics Regulation, it should at the very least have explained the reasons for this alleged lack of competence. This would have given the Appellant the possibility to contest the correctness of those reasons.

- *Whether the factsheet satisfies the duty to state reasons*

63. After the notification of the draft decision, the Agency and the Appellant held a telephone conference on 30 October 2015. The Appellant raised its concerns about the implications of the Cosmetics Regulation for the draft decision. The Agency mentioned the existence of the factsheet on its website.

64. However, the existence of the factsheet, even if referred to during the telephone conference, does not satisfy the duty to state reasons for the following reasons.

65. First, with regard to testing proposals, the Agency prepares a draft decision and notifies it, together with the comments of the addressee, to the competent authorities of the Member States. This is in accordance with the procedure for decisions on testing proposals under dossier evaluation set out in Articles 40, 50 and 51 of the REACH Regulation. The Agency subsequently adopts the decision if the competent authorities of the Member States agree to it unanimously.

66. If the Agency's interpretation of the relationship between the REACH Regulation and the Cosmetics Regulation had been explained in the Contested Decision, it would be clear that the competent authorities of the Member States had unanimously and expressly agreed with that interpretation by adopting the decision. The Appellant therefore had a particular interest that the Contested Decision should be thoroughly reasoned as regards the Agency's interpretation of the relationship between the REACH Regulation and the Cosmetics Regulation.

67. The possible enforcement of the marketing ban under the Cosmetics Regulation rests with the Member States. If the Contested Decision had contained reasoning as to why the Agency considered that performing the required test would not lead to a marketing ban for the Substance, and the competent authorities of the Member States had unanimously and expressly agreed to those reasons, the Appellant would have been in a less legally uncertain position.

68. Second, the factsheet is not in itself a binding legal instrument. In order for the Appellant to be able to rely on it, or to contest it, the Contested Decision should have referred to it expressly.

69. Third, the minutes of the telephone conference state that '*[t]he communications made by [the Agency] during the telephone conference cannot be regarded as a formal opinion or position of [the Agency] concerning specific scientific or regulatory issues on the current draft decision*'. Therefore, information given during the telephone conference cannot be regarded as being part of the statement of reasons for the Contested Decision. In addition, any information given during the teleconference has not been formally agreed by the competent authorities of the Member States following the procedure for decisions on testing proposals, as set out in Articles 40, 50 and 51 of the REACH Regulation.

70. Fourth, the Appellant expressly and repeatedly raised the issue of the use of the Substance and the potential marketing ban during the decision-making procedure, in particular in its comments on the draft decision. The Agency must provide an adequate statement of the reasons as to why the essential arguments of a party cannot be upheld (see judgment of 12 December 2000, *Alitalia* v *Commission*, T-296/97, EU:T:2000:289, paragraph 132 and the case-law cited).

71. In light of the above, neither the existence of the factsheet nor the reference to it during the telephone conference satisfy the requirements of the duty to state reasons.

72. Furthermore, according to the factsheet animal tests may be performed under the REACH Regulation unless (i) a substance is exclusively used in cosmetics, and (ii) there is no worker exposure. However, the Contested Decision does not address either of these conditions.

73. Therefore, even if the factsheet were a valid means of reasoning the Contested Decision as regards the relationship between the REACH Regulation and the Cosmetics Regulation, the fact remains that the Contested Decision does not explain how the interpretation set out in the factsheet applies in the present case.

- *Conclusion*

74. For the reasons stated above, the Agency breached the duty to state reasons.

75. The Contested Decision must therefore be annulled and remitted to the competent body of the Agency for further action. There is therefore no need to examine the remaining pleas in law.

Refund of the appeal fee

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

77. As the appeal is decided in favour of the Appellant, the fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls Decision TPE-D-2114344602-56-01/F of 21 September 2016.**
2. **Remits the case to the competent body of the Agency for further action.**
3. **Decides that the appeal fee must be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal