EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

27 October 2015

(Substance evaluation – Misuse of powers – Scope of substance evaluation – Exposure information – Proportionality – Duty to state reasons – Article 25(1))

Case number	A-006-2014
Language of the case	English
Appellant	International Flavors & Fragrances B.V., the Netherlands
Representative	James H. Searles, Ruxandra Cana and Anna Gergely Steptoe & Johnson LLP
Contested Decision	Decision of 25 February 2014 on the substance evaluation of hexyl salicylate adopted by the European Chemicals Agency pursuant to Article 46(1), and in accordance with the procedure laid down in Articles 50 and 52, 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 Decision was notified to the Appellant through the annotation number SEV-D-2114273859-29-01/F

THE BOARD OF APPEAL

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

Registrar: Sari Haukka

gives the following

Decision

Summary of the facts

1. On 26 May 2014, the Appellant lodged the present appeal at the Registry of the Board of Appeal in which it requested the Board of Appeal to annul the Contested Decision in so far as it requests the Appellant to update the registration dossier with the required new information, order the European Chemicals Agency (hereinafter the 'Agency') to refund the appeal fee paid by the Appellant, and take such other or further measures as justice may require.

2. In the event that the appeal should be found to be inadmissible or is dismissed, the Appellant requests the Board of Appeal to rule that the deadline set in the Contested Decision should be interpreted, in light of Article 91(2) of the REACH Regulation (all references to Recitals, Titles, Articles, and Annexes hereinafter concern the REACH Regulation unless stated otherwise), as referring to 15 months from the date of the final decision of the Board of Appeal.

Background to the dispute

3. On the basis of an opinion of the Agency's Member State Committee (hereinafter the 'MSC'), and due to initial grounds for concern relating to '[*h*]*uman health/Suspected CMR* [Carcinogenic, Mutagenic or Toxic for Reproduction properties]*; Exposure/Wide dispersive use, consumer use, high aggregated tonnage; Risk characterisation ratios close to 1 (human health)*', hexyl salicylate (hereinafter the 'Substance') was included in the Community rolling action plan (hereinafter 'CoRAP') for substance evaluation in 2012 (hereinafter 'CoRAP 2012') pursuant to Article 44(2). CoRAP 2012 was published on the website of the Agency on 29 February 2012. The evaluating Member State Competent Authority appointed was the Netherlands (hereinafter the 'eMSCA').

4. The Appellant is one of the joint registrants of the Substance. The joint registrants of the Substance are referred to hereinafter as the 'concerned registrants'. The Substance is used as an odour agent and is compounded into a number of fragrance mixtures that are formulated in low concentrations into consumer products.

5. On 28 August 2012, further to the eMSCA's invitation, two representatives of the Appellant (then a registrant) and two representatives of other concerned registrants attended a meeting related to the forthcoming evaluation of the Substance.

6. During the evaluation of the Substance, the eMSCA '*pointed out that the initial grounds for concern for human health was based on reproduction toxicity […]'.* The eMSCA however noted that additional information was needed to clarify an additional concern regarding local toxicity via the inhalation route. The eMSCA therefore prepared a draft decision pursuant to Article 46(1) to request further information which was submitted to the Agency on 27 February 2013.

7. On 4 April 2013, the Agency sent the draft decision to the concerned registrants and invited them, pursuant to Article 50(1), to provide comments within 30 days. On 6 May 2013, the concerned registrants provided comments to the Agency on the draft decision. The Agency notified the eMSCA of the comments received. In addition, the eMSCA considered the updates to the registration dossier made on 5 July 2013 by the lead registrant of the Substance. The dossier contained an updated Chemical Safety Report (hereinafter the 'CSR'). The update concerned

sections 1 to 8 of the CSR but not section 9 on exposure assessment. The eMSCA considered the concerned registrants' comments and amended Section II, 'information required', of the draft decision related to information on worker exposure assessment by removing the requirement to '*provide justification for the exposure assessment for 'Compounding' and 'Formulation' where PROC1* (Process category 1 denoting 'Use in closed process, no likelihood of exposure') *was used as process activity'* and the requirement to *'perform exposure measurements for cleaning activities'*.

8. On 5 September 2013, in accordance with Article 52(1), the eMSCA notified the Competent Authorities of the other Member States (hereinafter the 'MSCAs') and the Agency of its revised draft decision and invited them, pursuant to Articles 52(2) and 51(2), to submit proposals for amendment within 30 days. Proposals for amendment were subsequently received from two MSCAs and the Agency.

9. On 11 October 2013, the Agency notified the concerned registrants of the proposals for amendment to the draft decision and invited them, pursuant to Articles 52(2) and 51(5), to provide comments on those proposals for amendment within 30 days. The eMSCA reviewed the received proposals for amendment and further amended the revised draft decision accordingly.

10. On 21 October 2013, the Agency referred the amended draft decision to the MSC.

11. By 12 November 2013, the concerned registrants had provided comments on the amended draft decision. The eMSCA reviewed the comments received and did not amend the draft decision with the justification that no new information or data were provided.

12. After discussion at the MSC meeting of 10 to 13 December 2013, the open session of which was attended by a representative of the Appellant, a unanimous agreement of the MSC on the draft decision was reached on 12 December 2013.

13. The Contested Decision was adopted by the Agency and notified to the concerned registrants including the Appellant on 25 February 2014. The Contested Decision requested certain additional information for the Substance which can be summarised as follows:

    (a) An *in vitro* dermal absorption study using the test method specified in test method EU B.45 of Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1) or OECD test guideline (hereinafter 'OECD TG') 428 using freshly isolated skin and including quantification of possible metabolites, with specifications and with additional modifications of the test as set out in Section III of the Contested Decision;
    (b) A 28-day repeated dose toxicity study in the rat, by inhalation (test method EU B.8 of Regulation (EC) No 440/2008 or OECD TG 412);
    (c) An updated CSR related to:
        - worker exposure assessment;
        - risk management measures;
        - consumer exposure assessment for certain product codes;
        - certain information on air freshener products; and
        - a substance-specific justification for deviating from the default assessment factors to determine the Derived No-Effect Level (hereinafter 'DNEL') for substances as given in the Guidance on information requirements and chemical safety assessment (hereinafter the 'Agency Guidance'), Chapter R.8: Characterisation of dose [concentration]-response for human health.

Procedure before the Board of Appeal

14. On 26 May 2014, the Appellant lodged the present appeal at the Registry of the Board of Appeal.

15. On 14 July 2014, the Danish Environmental Protection Agency applied to intervene in the proceedings before the Board of Appeal in support of the Agency. By decision of 13 October 2014, the Board of Appeal, having heard the Parties, dismissed the application to intervene due to the fact that it did not comply with all the necessary requirements for intervention stipulated in Article 8 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').

16. On 30 July 2014, since the position of legally qualified member of the Board of Appeal was vacant, the Chairman, pursuant to the first subparagraph of Article 3(2) of the Rules of Procedure, designated an alternate member, Barry Doherty, to act in the present case as the legally qualified member of the Board of Appeal.

17. On 18 August 2014, the Agency submitted its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.

18. On 30 September 2014, the Appellant submitted its observations on the Defence.

19. On 11 November 2014, the Board of Appeal requested the Agency to respond to certain questions. On 12 January 2015, the Agency replied to those questions. On the same date, the Agency also lodged its observations on the Appellant's observations on the Defence.

20. On 11 March 2015, the Appellant submitted its observations on the Agency's observations of 12 January 2015.

21. On 26 March 2015, the Parties were notified of the Board of Appeal's decision to close the written procedure. On 9 April 2015, the Appellant requested that a hearing be held. On the same date the Agency informed the Board of Appeal that it did not request a hearing. In view of the Appellant's request, and pursuant to Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 16 June 2015. At the hearing, the Parties made oral presentations and responded to questions from the Board of Appeal.

Reasons

22. In support of the form of order sought in its appeal, the Appellant raises four pleas which can be summarised as follows.

23. First, the Appellant claims that the Agency exceeded the limits of its competence and misused its powers under the substance evaluation process. By requesting studies and information that are not material to the concerns identified for the inclusion of the Substance in the CoRAP. The Appellant contends that the listing of the Substance in the CoRAP identified potential CMR properties as the concern to be addressed through substance evaluation. Inhalation irritation properties were not identified, nor can they be expected to be considered '*of concern*' by reference to the other properties considered '*of concern*' in the context of the authorisation process and the expressed focus of the CoRAP listing. The Appellant also argues that by requesting additional exposure information the Agency exceeded the scope of its powers under Articles 44(1) and 46(1) and violated Article 11(1). The Appellant adds that the Agency cannot lawfully require further information which is related to producer specific exposure scenarios for workers and/or consumers.

24. Second, the Appellant claims that the Contested Decision is based on manifest errors of assessment related to the requirement for a 28-day repeated dose toxicity (hereinafter 'RDT') study in the rat, by inhalation. The Appellant argues that this study does not address skin irritation observed during acute exposure and will not result in an inhalation DNEL. By requiring a study which is not appropriate to address the alleged concerns the Contested Decision does not meet the 'necessity' test in the principle of proportionality.

25. Third, the Appellant claims that the Contested Decision lacks reasoning, in particular because it does not explain how the comments submitted by the Appellant were taken into account. In addition, according to the Appellant, the Contested Decision is flawed because it is not based on all relevant information that was available to the Agency.

26. Fourth, the Appellant claims that the Contested Decision was adopted in breach of Article 25.

The Appellant's first plea alleging that the Agency exceeded the limits of its competence and misused its powers under the substance evaluation process

27. The Appellant's first plea falls into two parts. The Appellant alleges that the Agency exceeded the limits of its competence and misused its powers under the substance evaluation process by requesting, firstly, the submission of information that is not material to the concerns identified for the inclusion of the Substance in the CoRAP and, secondly, by requesting additional exposure information. The Board of Appeal will examine these two aspects of the first plea in turn.

Arguments of the Parties

28. In support of the first part of its first plea, the Appellant states that the scope and limits of a substance evaluation must be assessed by reference to the justification for the initiation of the process and by reference to the outcome of the substance evaluation process.

29. The Appellant notes that substances with 'properties of concern' are prioritised for inclusion in the CoRAP. The Appellant adds that while the term 'properties of concern' is not defined, it must be understood by reference to the properties of concern identified in the context of the authorisation process. CoRAP 2012 focused on substances with potential persistent, bioaccumulative and toxic ('PBT'), endocrine disruption, and CMR properties, in combination with wide dispersive use and consumer exposure. In relation to the Substance, while its potential CMR properties were identified as a concern in CoRAP 2012, its inhalation irritation properties were not nor can they be expected to be considered 'properties of concern' by reference to the other properties considered to be of concern in the context of the authorisation process and the expressed focus of CoRAP 2012.

30. The Appellant claims further that potential regulatory outcomes of the substance evaluation, namely authorisation, restriction or classification and labelling, support a conclusion that the scope of the evaluation process must be limited to assessing properties of concern that could provide the basis for prioritisation in the first place, in this instance as a potential CMR and in particular as a potential developmental toxicant. The Appellant adds that any additional concerns that might be raised and investigated should be material and directly linked to the assessment of the initial or equivalent grounds for prioritisation.

31. The Appellant adds that once the 'properties of concern' that prompted inclusion of a substance in the CoRAP have not materialised during a substance evaluation, the process cannot thereafter refocus on other and lesser potential concerns which themselves could not have justified a substance's inclusion in the CoRAP in the first place. In the present case the Substance was included in CoRAP 2012 in relation to a concern for human health related to reproductive toxicity. The eMSCA then introduced an additional concern related to local toxicity via the inhalation route, without explaining or identifying any links between this additional concern and the initial concern.

32. The Appellant also claims that after the eMSCA had conceded that the initial developmental toxicity concern no longer needed to be addressed in the Contested Decision, the fact that the same decision requests information on a property that could not and did not form a basis for the Substance's initial inclusion in the CoRAP shows that the Agency exceeded the limits of its competence. Moreover, as local toxicity via inhalation would not qualify as a property 'of concern', by using substance evaluation for a purpose other than its intended purpose, the Agency misused its powers.

33. The Appellant concludes that, in requesting a study which the Agency admits will not result in a change to the classification of the Substance and will not serve as a basis for the assessment of possible further risk management measures to be adopted pursuant to the REACH Regulation, the Agency exceeded the limits of its competence under the substance evaluation process.

34. The Agency argues that the first part of the Appellant's first claim should be rejected since the Appellant's understanding of the substance evaluation process is not in line with the aim, purpose and objectives of the REACH Regulation. The substance evaluation provisions in the REACH Regulation must be read and applied having regard to the precautionary principle. The Agency considers that the objective and scope of substance evaluation are to clarify any possible concern related to a substance without prejudice to the outcome of that exercise.

35. The Agency states that when substances are included in the CoRAP they have not yet been evaluated and the concern is therefore indicative and not exhaustive or conclusive. The Agency's communication in that regard has been transparent and consistent.

36. The Agency further argues that the identified concern in the CoRAP neither limits an evaluating Member State's evaluation to that concern nor binds the Agency when issuing a substance evaluation decision. Inclusion of a substance in the CoRAP is the trigger for an assessment of the properties and exposure of that substance. Furthermore, substance evaluation should not be confused with a risk management option analysis or the initiation of possible regulatory risk management measures.

37. The Agency claims that the Appellant's interpretation of 'properties of concern', that is, only those concerns identified pursuant to the authorisation process, would severely limit the scope of substance evaluation. Furthermore, evaluating Member States should not be limited to assessing only those properties which could lead to further regulatory risk management measures.

38. As regards the Appellant's complaint that the Agency exceeded its competence by investigating further concerns in the Contested Decision, the Agency argues that the criteria for priority setting cannot be used as a limiting factor. Prioritisation for substance evaluation is a distinct process from the actual evaluation with the latter not being limited by the former. The Agency concludes that concerns identified

during the substance evaluation itself do not need to be linked with the initial concerns identified at the time of the CoRAP listing of the substance concerned.

39. In support of the second part of its first plea, the Appellant claims that the nature and objectives of dossier evaluation and substance evaluation and a teleological interpretation of the two processes suggest that further exposure-related information can be requested only as a result of the dossier evaluation procedure. Substance evaluation can only result in requests for information related to a substance's intrinsic properties. The Appellant argues that the Agency exceeded its powers under Articles 11(1), 44(1) and 46(1) and cannot lawfully require further information related to producer specific exposure scenarios for workers and/or consumers.

40. The Agency argues that although the information on uses and exposure is registrant-specific, such information can be provided to the Agency in a CSR jointly by multiple registrants, and *'[i]t is up to each individual registrant to find a way to meet the obligation to provide this data'*.

41. The Agency is of the opinion that exposure information is crucial in defining whether there is a concern that requires '*potentially further action, i.e. to check whether there is a risk associated with a substance or a particular use of that* substance'.

42. The Agency further argues that substance evaluation decisions are issued to '*all registrants concerned in their individual capacity as a registrant of a substance without any need to share confidential business information on uses or other types of potentially sensitive information*'. The Agency submits that its request in the Contested Decision does not require sharing such information with other registrants. The Contested Decision requests each addressee individually to provide the required information.

43. The Agency also claims that exposure information is a crucial element in establishing whether a risk exists and requesting such data therefore falls within the scope of the substance evaluation process. The Agency adds that exposure is listed as a criterion for priority setting for substance evaluation in Article 44 and is therefore of relevance when it comes to the assessment of the risk posed by a substance. Where exposure is uncertain, as in the present case, it is not clear whether there is a risk and the requested information should clarify the possible risk posed by the use(s) of the Substance. Consequently, '*both exposure information and hazard data are needed to establish whether risks to human health and the environment are properly controlled and whether safe use is warranted'*.

Findings of the Board of Appeal

44. At the outset, the Board of Appeal recalls that the REACH Regulation, as is clear from Article 1, aims to ensure a high level of protection of human health and the environment, the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Importantly, regard being had to Recital 16, it must be stated that the Community legislature established the first of those three objectives, namely to ensure a high level of protection of human health and the environment, as the main purpose of the REACH Regulation (see Case C–558/07, *S.P.C.M. and Others*, EU:C:2009:430, paragraph 45 and Case A-004-2014, *Altair Chimica SpA and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 39). The Board of Appeal considers that the substance evaluation process, as one of the pillars of the REACH regulatory

system, greatly contributes to the aim of the protection of human health and the environment.

45. In the light of the above, the Board of Appeal will examine the Appellant's claim that the Agency exceeded the limits of its competence and misused its powers under the substance evaluation process when requesting in the Contested Decision the submission of information not related to concerns identified for the Substance in the CoRAP and additional exposure information.

46. As regards the scope of substance evaluation and the inclusion of a substance in the CoRAP, the Board of Appeal observes that the objective of substance evaluation under the REACH Regulation is to allow, inter alia, for the generation of more information on the properties of a substance that is considered to constitute a risk to human health or the environment (see Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH and Others*, Decision of the Board of Appeal of 23 September 2015, paragraphs 56 to 58).

47. As regards the criteria for substance evaluation, Article 44(1) provides, inter alia, that '*in order to ensure a harmonised approach, the Agency shall in cooperation with the Member States develop criteria for prioritising substances with a view to further evaluation*. *Prioritisation shall be on a risk-based approach.'* Article 44(1) also provides that, when setting the criteria for prioritisation of substances, the Agency and the Member States need to consider hazard information, exposure information, and (aggregated) tonnage.

48. The Board of Appeal observes that the processes of establishing the CoRAP and the evaluation of a substance included in the CoRAP are separate, although linked, processes. The process establishing the CoRAP relies on risk-based criteria which are used to select substances for inclusion in the CoRAP. Inclusion in the CoRAP means that the substance will subsequently be evaluated pursuant to the substance evaluation process.

49. The Board of Appeal notes that in the present case, as mentioned in paragraph 3 above, CoRAP 2012 included the initial grounds of concern that led to the inclusion of the Substance in the CoRAP. The Board of Appeal observes that the REACH Regulation does not require that the relevant risk based criteria which lead to the inclusion of a substance in the CoRAP needs to be identified in the CoRAP. The Board of Appeal further observes that, while it is the Agency's practice to indicate in the CoRAP the concern(s) that led to a substance's inclusion therein, the identification of initial grounds for concern cannot be interpreted as restricting or limiting the scope of the substance evaluation process. Such an approach would ignore any new concerns which are identified after the substance evaluation procedure began, and so potentially overlook threats to human health or the environment.

50. The above finding of the Board of Appeal is supported by Article 47(1) which provides that '*an evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation […]*'. The Board of Appeal therefore finds that the Appellant's conclusion that substance evaluation should be in principle limited to the grounds used for a substance's inclusion in the CoRAP is not supported by the REACH Regulation nor is it consistent with its primary aim of protection of human health and the environment.

51. Whilst not decisive in this regard, the Board of Appeal notes that this position is consistent with the Guidance on Dossier and Substance Evaluation (June 2007), applicable throughout the evaluation of the Substance, which stated under point 3.2.1 on principles for targeting substance evaluation that *'[n]ormally, the*

[Member State] does not need to look at issues unrelated to the grounds for concern, but it may choose to do so in case it is worried in general about the quality of assessment and exposure scenarios for the substance. A balance needs to be found between a straight forward and efficient procedure and the goal to cover of [sic] *all grounds for concern.'*

52. Furthermore, the Board of Appeal notes that its position is also consistent with the text accompanying CoRAP 2012 where it is stated that *'[t]he indication of the ground of concern does not limit the evaluation made by the Member States, since the Members States may also focus their assessment into other concern areas they find relevant during the evaluation'*. The Agency has therefore made it clear that, as far as it is concerned, a substance evaluation could go beyond the concern(s) that lead to the substance being included in the CoRAP in the first place.

53. As regards the Appellant's claim that the Agency misused its powers by using substance evaluation for something other than its intended purpose, that is because local toxicity via inhalation would not qualify as a property 'of concern' and did not form a basis for the Substance's initial inclusion in the CoRAP, the Board of Appeal notes that this claim is based on the assumption that there is no concern which the Agency could legitimately have investigated. As there was a concern regarding short-term inhalation toxicity from exposure to the Substance, as explained under the second plea (see paragraph 64 et seq), the Board of Appeal finds that this assumption is unfounded.

54. Moreover, the Board of Appeal observes that the concept of misuse of powers refers to cases where an administrative authority has used its powers for a purpose other than that for which they were intended. A decision amounts to a misuse of powers only if it appears, on the basis of objective, relevant and consistent factors, to have been taken to achieve an end other than that stated (see, for example, Case T-31/07, *Du Pont de Nemours (France) SAS and Others* v *Commission*, EU:T:2013:167, paragraphs 334 to 335). In the present case, other than its claim as to the misuse of powers by the Agency, the Appellant has submitted no evidence from which it may be concluded that the Contested Decision and the substance evaluation in question was concluded with an aim to achieve an end other than that stated in the Contested Decision.

55. In conclusion, in relation to the first part of the Appellant's first plea, the Board of Appeal finds that the priority setting exercise for substances to be included in CoRAP must identify those substances that potentially pose a risk to human health and the environment. The subsequent assessment of substances in CoRAP is not limited to the concern(s) that led the Agency to include that substance in CoRAP in the first place. Consequently, the Board of Appeal finds that the Appellant's first part of the first plea arguing that, in the present case, the Agency exceeded the limits of its competence and misused its powers under substance evaluation by requesting the submission of information that is not related to concerns identified for the Substance in CoRAP 2012, is unfounded.

56. Next, the Board of Appeal will examine the second part of the Appellant's first claim that the Agency's request for further information related to producer specific exposure scenarios for workers and consumers was unlawful.

57. The Board of Appeal considers that with this claim the Appellant in essence questions whether the Agency was allowed under substance evaluation to request additional exposure information.

58. The Board of Appeal observes that the Substance is registered collectively at 1000 - 10 000 tonnes per annum. Moreover the Substance is classified as a skin irritant and skin sensitiser and has numerous uses that may result in the widespread exposure of workers and consumers to the Substance.

59. The Board of Appeal notes that the Contested Decision requested the concerned registrants, including the Appellant, to provide exposure information in order to further examine the risks to workers from exposure to the Substance. Moreover, the Contested Decision requested information on consumer exposure to certain products categories as the Agency considered that there is insufficient information to conclude on whether risks to consumers are sufficiently controlled.

60. The Board of Appeal accepts that the information requested regarding exposure of workers and consumers from individual registrants could potentially have been requested following a compliance check of individual registration dossiers under the dossier evaluation procedure.

61. The Board of Appeal finds however that first, the exposure information requested by the Contested Decision is not standard information in the context of registration. This information would not necessarily therefore be requested following a compliance check of a registration dossier. Second, whilst the Contested Decision requests information from individual registrants, this request results from a substance evaluation procedure whereby the eMSCA and the Agency have access to a far wider pool of information on the uses of the Substance than would otherwise be available during a compliance check of the individual registration dossiers. The possibility provided by the substance evaluation process to look at *'all relevant information submitted*' on the Substance, that is all the registration dossiers, could help in the identification of information needs on exposure from individual registrants that could be pertinent to the wider risk assessment and management of the Substance. In particular, by examining all relevant information submitted on a substance it may become more apparent that further exposure information is needed than would be the case by examining a single registration dossier and the uses covered by it. Third, it would be time consuming and inefficient for the Agency to undertake compliance checks of several registration dossiers in order to adopt decisions to help clarify the potential risk identified during a substance evaluation. Moreover, such an approach would run contrary to the primary objective of the REACH Regulation which is to ensure a high level of protection of human health and the environment.

62. In light of paragraphs 58, 59 and 61 above and due to the fact that the Contested Decision identified the potential risk regarding short-term inhalation toxicity from exposure to the Substance (see paragraphs 81 to 88 below), the Board of Appeal finds that the Agency was justified in the present case in making requests regarding exposure information to individual registrants pursuant to the substance evaluation procedure at issue. The Agency has therefore not exceeded the scope of its powers and, as a result, the Board of Appeal finds that the Appellant's second part of the first plea is unfounded.

63. Having regard to all of the foregoing considerations, the Board of Appeal holds that none of the arguments put forward by the Appellant in support of the first plea are capable of establishing that the Agency exceeded the limits of its competence and misused its powers during the evaluation of the Substance. In these circumstances, the Appellant's first plea must be rejected.

The Appellant's second plea alleging that the Contested Decision is based on manifest errors of assessment related to the requirement for a 28-day RDT study, in the rat, by inhalation and infringes the principle of proportionality

Arguments of the Parties

64. In support of its second plea, the Appellant argues that the Agency's request for a 28-day RDT study is based on manifest errors of assessment and infringes the principle of proportionality.

65. The Appellant argues, in particular, that firstly, the Agency recognises that the result of the requested study would not contribute to a classification of the Substance as hazardous. Secondly, requesting a study on repeated inhalation exposure could not substantiate a concern based on skin irritation observed during repeated skin exposure. Moreover, the concern for respiratory irritation is expected to be low as the Substance is only slightly irritating to eyes and the air/water barrier of the eye may reflect better the lung barrier than the skin barrier. The Appellant also notes that the irritant properties observed during oral exposure for salicylates in general and in a relevant study were taken into account in the DNEL for repeated exposure and argues that the DNEL is sufficiently precautionary for local and systemic effects. Furthermore, the requested 28-day RDT study will not result in an inhalation DNEL. Thirdly, the request for a 28-day RDT study with reference to the Substance's skin irritant properties cannot be justified because, the Substance being a skin sensitiser cannot be assumed to mean that it is also a respiratory sensitiser, a route-to-route extrapolation from skin irritation/sensitisation to respiratory irritation cannot be applied, and the Substance does not have properties that are indicative of a concern for respiratory irritation. The Appellant argues, fourthly, that the Substance's low volatility indicates minimal inhalation exposure, that the inhalation route is only a minor route of exposure, and that all Risk Characterisation Ratios (hereinafter 'RCRs') regarding inhalation exposure for all life cycle steps are well below 1.

66. The Agency claims that the request for a 28-day RDT study by inhalation is based on a robust scientific justification and meets the proportionality criteria. The request is based on a concern that the Substance could exhibit local toxicity via the inhalation route. The Agency adds that local irritation effects, either mediated by irritation or hypersensitivity could have a serious impact on human health. The Substance's adverse health effects that occur at the area of contact, for example skin and mucous membrane of the eye, the lack of inhalation data, and the possible inhalation exposure of workers and consumers to the Substance, lead to a concern for local effects in the respiratory tract, which is not sufficiently addressed in the available data. As no data addressing this concern are currently available the Contested Decision requested the generation of such data.

67. The Agency argues that the Appellant's arguments related to the Substance's skin irritation properties remain speculative as no information is currently available that would give a sufficiently clear answer as to possible adverse effects on lungs caused by inhalation of the Substance. There are no inhalation data for any analogue substances that have similar properties to the Substance. The Agency also notes that predicting properties using a read-across approach is endpoint-specific and the route of administration has to be considered before accepting a proposed read-across. Consequently, further data are needed to clarify the concern.

68. The Agency adds that the 28-day RDT study will be an important consideration in reaching a conclusion on whether there is any local toxicity via inhalation.

69. The Agency further submits that the fact that the Substance elicits local effects (irritation and sensitisation) on the skin and is mildly irritating to the eyes leads to the concern that exposure via inhalation may result in local effects in the respiratory tract. This concern can only be removed if it can be shown that no exposure via the respiratory tract occurs throughout the life cycle of the Substance or that exposure is below the local inhalation DNEL. However, there are clear indications in the registration dossier of potential inhalation exposure for which the information provided in the dossier does not allow the setting of a DNEL for local effects after inhalation exposure. There are no justifications that the exposure is sufficiently low and a concern remains for the safety of workers and consumers.

70. The Agency concludes that the Contested Decision does not exceed what is necessary to meet the objective of substance evaluation as the requested information is necessary to clarify the concern for local effects in the respiratory tract posed by the Substance. The requested information is necessary to clarify that concern since the Substance is produced in high volumes and is used in a wide range of products resulting in potential widespread exposure of workers and consumers to the Substance. Moreover, the registrations for the Substance are built on a read-across approach using five substances for which no information on inhalation toxicity is provided.

Findings of the Board of Appeal

71. The Board of Appeal will, firstly, address the Appellant's claims regarding the violation of the principle of proportionality and, secondly, consider the claims regarding manifest errors of assessment.

72. The Board of Appeal recalls that the principle of proportionality requires that European Union measures do not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see Case C-15/10, *Etimine SA* v *Secretary of State for Work and Pensions*, EU:C:2011:504, paragraph 124 and the case-law cited and Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH and Others*, Decision of the Board of Appeal of 23 September 2015, paragraph 52).

73. The Board of Appeal will therefore examine whether, in the present case, the requested measure was necessary, appropriate and the least onerous option.

74. To this effect, the Board of Appeal notes that according to Recital 20 the objective of the substance evaluation process is the '*generation of more information on the properties of substances'* when there are '*grounds for considering that a substance constitutes a risk to human health or the environment, […]*'.

75. The Board of Appeal further observes that Recital 63 sets out a general principle according to which '*[i]t is also necessary to ensure that generation of information is tailored to real information needs […]*'. Article 48, which links the results of substance evaluation to restrictions, authorisation and harmonised classification and labelling, indicates that substance evaluation is primarily designed to clarify risks with risk management measures in mind. The Board of Appeal therefore considers that substance evaluation is intended to assess risks that may occur in reality and not purely theoretical risks.

76. In light of the above, the Board of Appeal considers that, under substance evaluation, in order to request additional information consistent with the proportionality principle, the Agency must inter alia be able to demonstrate the

necessity of the requested measure by setting out the '*grounds for considering that a substance constitutes a risk to human health or the environment*'. The Agency must also be able to demonstrate that the potential risk needs to be clarified, and that the requested measure has a realistic possibility of leading to improved risk management measures (see by analogy Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH and Others*, Decision of the Board of Appeal of 23 September 2015, paragraphs 56 to 60).

77. The Board of Appeal notes that this approach is consistent with the European Union Courts' interpretation of the precautionary principle which states that '*a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken*' (see Case T-13/99, *Pfizer Animal Health SA* v *Council*, EU:T:2002:209, paragraph 144).

78. It is in the light of those considerations that the Board of Appeal will examine the arguments put forward by the Appellant in support of its plea alleging that the Agency violated the principle of proportionality by requiring a 28-day RDT study during the evaluation of the Substance in the present case.

79. The Board of Appeal notes that the Agency explained in the Contested Decision that additional information on the potential hazard posed by the Substance with regard to short-term inhalation toxicity will be acquired by means of a 28-day RDT study by inhalation. The Board of Appeal also notes that the Contested Decision requests information on exposure in order to evaluate the risks posed to workers from exposure to the Substance. The Contested Decision also requests information related to consumer exposure. According to the Agency, the requested information will clarify whether there is a concern for local toxicity via the inhalation route from the use of the Substance, in other words, whether there is a risk that needs to be further managed.

80. Before considering whether the requested study was necessary, the Board of Appeal will examine whether the objective pursued by the study was sufficiently clear.

81. The Contested Decision states that '*[i]nformation on short-term inhalation toxicity is required in order to address a concern on local toxicity via the inhalation route*' and later that the results of the requested study '*possibly resulting in the most critical endpoint for the derivation of an inhalation DNEL for local effects*' and later still that '*[w]hether or not the resulting exposures can be considered negligible cannot be determined if there is no inhalation DNEL established covering also possible local effects*'. The Board of Appeal also notes that at the oral hearing the Agency clarified that, by requesting the 28-day RDT study, the Contested Decision sought to establish whether there is any local toxicity via the inhalation route and consequently to derive an inhalation based DNEL. Once the DNEL was derived it would be possible to establish if there is a concern as a result of exposure. At the oral hearing the Appellant stated that the objective pursued had changed from classification of the Substance for inhalation toxicity and restrictions based on a DNEL to examining the effects on workers and consumers from exposure by inhalation to the Substance. The Agency clarified at the oral hearing that its submissions in the present case had only addressed the sensitisation endpoint because this had been raised by the Appellant and not because this was an objective of the requested study.

82. The Board of Appeal finds that it is sufficiently clear from the wording of the Contested Decision that the objective pursued by the request for the 28-day RDT study is to clarify the concern for short-term inhalation toxicity in light of the

possible exposure of workers and consumers to the Substance and, if appropriate, to derive an inhalation DNEL for local effects.

83. The Board of Appeal therefore finds that in relation to the proportionality test outlined in paragraph 72 above the objective pursued by the measure was made sufficiently clear in the Contested Decision.

84. Having identified the objective pursued, the Board of Appeal will next examine whether the information to be acquired, by means of a 28-day RDT study, was necessary to achieve that objective. To this effect, the Board of Appeal will determine whether the Agency set out the '*grounds for considering that a substance constitutes a risk to human health or the environment*', that this potential risk needs to be clarified, and that the measure requested has a realistic possibility of leading to improved risk management measures. The Board of Appeal observes that the '*grounds for considering that a substance constitutes a risk to human health or the environment*' must be based on a combination of hazard and exposure information.

85. The Board of Appeal notes that the Agency Guidance, Chapter R.7a: Endpoint specific guidance, Version 2.0, November 2012 (hereinafter the 'Agency Guidance, Chapter R.7a') states under '7.2.4.2 Human data for irritation/corrosion' that '*[o]ften the only useful information on respiratory irritation is obtained from human experience (occupational settings)*'. The Agency Guidance, Chapter R.7a also states under 'R.7.2.1.2 Objective of the guidance on skin- and eye irritation/corrosion/respiratory irritation' that '*[...] account should be taken of any existing and available data that provide evidence of the respiratory irritation potential of a substance. Moreover, the data on local dermal or ocular corrosion/irritation might contain information that is relevant for the respiratory endpoint and this should be considered accordingly*'.

86. The Contested Decision, referring to the '*technical dossier on the registered substance*', indicates that the concerned registrants, including the Appellant, classified the Substance as a skin irritant (category 2) and skin sensitiser (category 1) as a result of scientific data available on the Substance. In relation to eye irritation, the Board of Appeal notes that at the oral hearing the Agency stated that a considerable number of notifiers to the Classification and Labelling Inventory, published on the Agency's website pursuant to Article 42 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1) self-classified the Substance for eye irritancy as well. The Agency also referred in the Contested Decision and in these proceedings to toxicological data showing mild eye irritation properties. The Board of Appeal also notes that the Substance exhibits a variety of adverse local effects at the area of contact, for example to the skin, and the mucous membrane of the eye.

87. The Agency's premise, in part, is that there is evidence of skin and eye effects due to exposure to the Substance and that this indicates that exposure via inhalation may lead to local respiratory effects. The Appellant argued that the results of an oral repeat dose test conducted on an analogue are sufficient to address the respiratory irritation endpoint for the Substance. The Board of Appeal notes however that the analogue did not exhibit similar irritant properties to the skin and eye as the Substance. The Board of Appeal finds that a lack of local effects demonstrated by tests on an analogue that is not known to have similar irritant properties to the target substance is not conclusive evidence that the target substance is not a respiratory irritant. As noted above, the Agency has identified

information regarding local toxicity to skin and eye which in the case at issue are potentially indicators of local respiratory irritation. The Board of Appeal finds that the Agency's approach in this regard is therefore appropriate as the data available on dermal and eye irritation indicates a potential hazard regarding respiratory irritation. The Board of Appeal notes that this approach is consistent with the Agency Guidance, Chapter R.7a which indicates that local dermal or ocular irritation is potentially relevant for the respiratory endpoint (see paragraph 85 above).

88. The Board of Appeal accepts that establishing whether a substance causes local respiratory effects cannot be achieved by extrapolation from one route of exposure to another. In this regard the Contested Decision states that '*according to [the Agency] guidance, route-to-route extrapolation from the oral to the inhalation route to derive an inhalation DNEL for local effects should not be applied*'. The Board of Appeal, firstly, notes that the Appellant's interpretation of the Agency Guidance, Chapter R.7a would negate its own argument that a repeat dose dermal study is sufficient, with certain other information, to address the respiratory irritation endpoint as this would entail extrapolating from one route of exposure to another. The Board of Appeal considers, secondly, that the purpose of requesting the 28-day RDT study is precisely because this extrapolation is not possible. As a result, in order to determine if there is a local respiratory effect, assuming such a concern is adequately justified, specific testing via inhalation is needed.

89. The Board of Appeal also notes that the Agency Guidance, Chapter R.7a states under 'R.7.2.1.2 Objective of the guidance on skin- and eye irritation/corrosion/respiratory irritation' that '*[i]t is for instance a reasonable precaution to assume that corrosive (and severely irritating) substances would also cause respiratory irritation when vaporised or in form of aerosol […]*'. The Board of Appeal observes that this guidance is intended to help in the identification of hazardous properties of substances. In the context of a substance evaluation the intention of a further information request is to clarify concerns without extrapolating from one effect to the other. The Board of Appeal also observes that the Substance may be used by workers and consumers when vaporised or in the form of an aerosol. The Board of Appeal finds that there is therefore no contradiction in the Agency Guidance, Chapter R.7a referring to severely irritating substances causing respiratory irritation and a request, if adequately justified, for further information on a substance that is 'only' an irritant to clarify whether it causes respiratory irritation.

90. Further to the above considerations, the Board of Appeal finds that the Agency did not act in contradiction with its guidance in its identification of the hazard or in its choice of the requested study.

91. As regards potential exposure to the Substance, the Board of Appeal notes that the Substance is registered collectively at 1000 - 10 000 tonnes per annum. The Board of Appeal further notes that the Substance functions as an odour agent and is compounded into different fragrance mixtures. These fragrance mixtures are formulated in low concentrations into consumer products and used in sprays and other consumer products. Workers are therefore at risk of being exposed to the Substance during manufacturing processes unless exposure is completely avoided. The Substance is also inevitably going to be inhaled by consumers in some uses. The Appellant submitted that the Substance's low volatility and low concentration in mixtures and spray applications suggest that there is low exposure to the Substance. The Board of Appeal acknowledges the pertinence of these arguments to the assessment of exposure of workers and consumers to the Substance. These arguments cannot, however, undermine the conclusion that, prima facie, there is significant exposure of consumers and workers to the Substance as evidenced by

the widespread worker and consumer use of the Substance coupled with the high tonnage manufactured in and imported into the European Union every year.

92. The Board of Appeal notes that the information submitted in response to the requests in the Contested Decision for information on short-term inhalation toxicity, coupled with additional exposure information, may lead to improved risk management measures. At the oral hearing the Appellant stated that it understood that the purpose of the requested 28-day RDT study is to derive a '*new DNEL for local effects in inhalation*'. In this regard, the Board of Appeal notes that the existing DNEL was based on systemic effects following oral exposure to the Substance. The Contested Decision explains the purpose of requesting the 28-day RDT study was that '*possible effects resulting from hypersensitive reactions to the [Substance] might be observed in an inhalation 28-day study, […] possibly resulting in the most critical endpoint for the derivation of an inhalation DNEL for local effects*'. In light of the lack of inhalation data for the Substance, the Board of Appeal accepts that the derivation of a DNEL for local inhalation effects is, in the present case, legitimate and justified, as it may contribute to improved risk management measures.

93. Whilst the evidence regarding the hazard, namely short-term inhalation toxicity, is inconclusive, the exposure potential is clear, and this, coupled with the fact that there is no inhalation derived DNEL available, leads the Board of Appeal to conclude that the Agency has adequately justified its grounds for considering that the Substance constitutes a potential risk to human health and that this potential risk needs to be examined further. Therefore, the Board of Appeal finds that the information to be acquired by means of a 28-day RDT study was necessary.

94. The Board of Appeal will next examine whether the 28-day RDT study is appropriate to satisfy the objective pursued. The Board of Appeal notes that the Agency explained in the Contested Decision why the 28-day RDT study is suitable in relation to the pursued aim, *'possible effects resulting from hypersensitive reactions to the [Substance] might be observed in an inhalation 28-day study, for example, in gross pathology of the draining lymph nodes of the lung, possibly resulting in the most critical endpoint for the derivation of an inhalation DNEL for local effects'*.

95. The Board of Appeal also recalls that the 28-day RTD study is specifically identified in the Agency's Guidance as being appropriate for the consideration of respiratory irritation. The Agency Guidance, Chapter R.7a, states under 'R.7.2.3.1 Non-human data on irritation/corrosion', in relation to 'respiratory irritation' that '*[…] histopathological examination of respiratory tract tissues of animals repeatedly exposed by inhalation (28-day and 90-day inhalation studies) may provide information on inflammatory/cytotoxic effects such as hyperemia, edema, inflammation or mucosal thickening*'. The Board of Appeal notes that any local effects in the respiratory tract due to either irritation or sensitisation reactions should be seen in a well-conducted 28-day RTD study.

96. The Board of Appeal therefore finds that in relation to the proportionality test outlined in paragraph 72 above the request for the 28-day RDT study is an appropriate measure to satisfy the objective pursued.

97. The Board of Appeal will next examine whether the 28-day RDT study is the least onerous measure to satisfy the objective pursued. At the oral hearing the Appellant suggested that a review of human data in an epidemiological study may be appropriate to meet the objective pursued. The Board of Appeal finds that the Appellant has not substantiated its claim that an epidemiological study may be appropriate nor has it demonstrated how the results of an epidemiological study might be used to satisfy the objective pursued. The Board of Appeal observes that

there are many confounding factors to consider in any epidemiological study and that the relevance of the results may be uncertain especially when the target groups are, as in this case, exposed to many different chemicals. Moreover, the Board of Appeal has no information on the cost of such a study which would allow it to conclude that an epidemiological study would be a less onerous requirement than a 28-day RTD study. The Board of Appeal therefore, in the absence of an adequate justification to address the many confounding factors which prima facie would be present in this particular case, rejects the claim that an epidemiological study would be a less onerous approach to satisfy the objective pursued. The Board of Appeal also notes that a 90-day RTD study could potentially have been requested (see paragraph 95 above) by the Agency but this would have been significantly more onerous than a 28-day RTD study. The Board of Appeal concludes that the Appellant has not suggested a less onerous viable alternative to the 28-day RTD study to satisfy the information requirement.

98. The Board of Appeal therefore finds that in relation to the proportionality test outlined in paragraph 72 above the request for the 28-day RDT study is the least onerous measure to satisfy the objective pursued.

99. Whilst not decisive, the Board of Appeal notes that consideration of short-term inhalation toxicity raises complex problems regarding both the conduct of testing and assessment of the results in order to derive a DNEL for local respiratory effects. Likewise, the Board of Appeal also observes that if the results of the requested 28-day RDT study demonstrate a local respiratory effect further examination might be needed, as part of a stepwise approach, to distinguish between whether any effects have been caused by irritation or sensitisation and/or to substantiate an allergic mechanism. The Agency should therefore consider what further advice and guidance it could provide in this and other similar cases as regards the conduct of, and follow-up to, requested studies to help ensure that the maximum benefit is obtained from such testing. The Board of Appeal notes however that, in the circumstances of the present case, the Agency was justified in finding that there was no alternative to the requested study to address the identified concern.

100. In conclusion, the Board of Appeal finds that the 28-day RDT study requested by the Agency is appropriate and necessary for the objective pursued by the Contested Decision and the disadvantages caused are not disproportionate to the aims pursued. Furthermore, the Appellant has not demonstrated that there are less onerous options to satisfy the objective pursued by the Contested Decision. Having regard to all of the foregoing considerations, it must be held that none of the arguments put forward by the Appellant in support of the second plea are capable of establishing that the Agency breached the principle of proportionality. In light of the above, the Board of Appeal finds that the request in the Contested Decision for a 28-day RTD study was not disproportionate and this claim must therefore be dismissed as unfounded.

101. The Board of Appeal will next conclude on the related claims that the Contested Decision is based on manifest errors of assessment. When an appellant claims that the Agency has made a manifest error of assessment, the Board of Appeal must in particular examine whether the Agency has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached (see, in that sense, Case T-71/10, *Xeda International and Pace International* v *Commission*, EU:T:2012:18, paragraph 71, confirmed on appeal by judgment in Case C-149/12 P, *Xeda International and Pace International* v *Commission*, EU:C:2013:433 and Case A-004-2014, *Altair Chimica SpA and Others*, cited in paragraph 44 above, paragraph 42). In light of its analysis above on the proportionality of the request for a 28-day RTD study, the Board of Appeal finds

that the Appellant has not demonstrated that the Agency failed to examine, carefully and impartially, all the relevant facts in arriving at the relevant conclusions in the Contested Decision.

102. Whilst the Appellant clearly indicates why it does not agree with the conclusions reached by the Agency in the Contested Decision, the Board of Appeal finds that in light of its analysis above in the context of the proportionality test, the Appellant did not demonstrate any errors of assessment on the part of the Agency.

103. The Appellant's arguments alleging manifest errors of assessment related to the requirement for a 28-day RDT study must therefore be dismissed.

104. Further to the above, the Board of Appeal concludes that the second plea regarding proportionality and manifest errors of assessment must be dismissed as unfounded.

The Appellant's third plea alleging that the Contested Decision lacks reasoning

Arguments of the Parties

105. In support of its third plea, the Appellant argues that the Contested Decision does not provide sufficient justification for requesting the studies and exposure information contained therein. Furthermore, it does not explain why the arguments submitted by the Appellant on the draft decision have been rejected. The Appellant considers that, in highly technical and complex matters such as the present one, it is not sufficient to merely state that the '*comments have been taken into account*' since it does not allow the Appellant to know why its arguments were dismissed. In this case particularly with respect to the requested *in vitro* dermal absorption study.

106. The Appellant also claims that the Contested Decision is flawed because it is not based on all relevant information that was available to the Agency, in particular in relation to comments that the Appellant made to the request for information on worker exposure. The Appellant argues that, under Article 51(5), the Agency cannot artificially restrict its obligation to take comments into account, and every comment received from the registrant during commenting period must be assessed.

107. The Agency claims that the Contested Decision includes the required level of clarity and detail that a statement of reasons should have.

108. The Agency submits that it considered all comments made by the Appellant in accordance with the procedural guarantees set out in the REACH Regulation, and did not consequently breach the Appellant's right to be heard.

109. The Agency concludes that it has provided a robust justification for the Contested Decision and that it has been transparent from the beginning in explaining that no updates submitted after referral of the draft decision to the eMSCA will be considered. It also explained in the Contested Decision that some of the comments made by the Appellant were also outside the scope of commenting at that stage of the decision-making procedure.

Findings of the Board of Appeal

110. At the outset, the Board of Appeal observes that 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 Board of Appeal to exercise its power of review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each 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. It is not necessary for the reasoning to go into all the relevant facts and points of law since the question of whether the statement of reasons meets the requirements of Article 296 of the Treaty on the functioning of the European Union must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (see Case C-367/95 P, *Commission* v *Sytraval and Brink's France*, EU:C:1998:154, paragraph 63).

111. The Board of Appeal also observes that the adequacy of the reasons given in a decision is assessed with reference to the context of the decision. The requirements of the duty to state reasons can be attenuated if the measure in question was adopted in circumstances known to the affected person which enable it to understand the scope of the measure. This is the case where a party was closely involved in the process by which the contested decision came about and is therefore aware of the reasons for which the administration adopted it (see, for example, Case A-004-2014, *Altair Chimica SpA and Others*, cited in paragraph 44 above, paragraph 130 and the case-law cited).

112. The Board of Appeal observes that, in the case at issue, the Appellant was closely involved in the administrative process leading to the adoption of the Contested Decision and actively participated in all phases of the substance evaluation process. Moreover, the Appellant has used several opportunities to provide comments to the eMSCA and the Agency during the substance evaluation procedure. The Board of Appeal finds that the Appellant is, therefore, in a position to understand the scope of the Contested Decision and to ascertain the reasons behind it.

113. As regards the Appellant's claim that the Agency failed to provide sufficient justification for requesting a 28-day RDT study, the Board of Appeal already found when examining the Appellant's second plea that the Agency appropriately and sufficiently justified its conclusions. It is therefore sufficient to mention that the Board of Appeal finds that the Contested Decision states the reasons that led the Agency to require that information. The Contested Decision explains the objective of the requested study and why, in view of the information available, namely the grounds for concern regarding the properties of the Substance and exposure of workers and the general public via the inhalation route, the study should be carried out.

114. As regards the Appellant's claim that the Agency failed to provide sufficient justification for requesting additional exposure information, the Board of Appeal considers that the Agency, in light of the scope of substance evaluation, was justified in requesting such information and also appropriately justified it in its Contested Decision (see paragraphs 61 to 62 above). Moreover, related to the requested information on worker exposure, the Board of Appeal observes that the Contested Decision states that '*the information requested on worker exposure is required to evaluate the exposure and risks of workers working with or exposed to the [Substance]*'. The Contested Decision also mentions that the concerned registrants' additional comments pursuant to the proposals for amendment to the draft decision from the MSCAs and the Agency were not considered in detail as they were unrelated to those proposals.

115. As regards the Agency's request in the Contested Decision for an *in vitro* dermal absorption study, the Board of Appeal considers that the Agency's reasons are stated extensively and in detail in the Contested Decision. It is stated therein that information on dermal absorption is required in order to enable the eMSCA to assess the exposure and risk after dermal exposure to the Substance. Furthermore, the Contested Decision provides reasons as to why the reliability of two dermal absorption prediction models provided by the concerned registrants in the update of the registration dossier in July 2013 were considered to be questionable as regards establishing the dermal absorption of the Substance. The Board of Appeal also notes that an 'overview' proposed, by the concerned registrants, to derive a dermal absorption fraction for the Substance available at the start of the substance evaluation procedure was considered by the eMSCA during that procedure and found to be unreliable. As shown in the minutes of an informal meeting between the eMSCA and the Appellant, that finding was also communicated to the Appellant. The Board of Appeal finds that it is clear therefore that all the information regarding dermal absorption available up to and including 5 July 2013 was fully considered during the substance evaluation process and that this was made clear to the Appellant during the decision-making process and in the Contested Decision.

116. The Board of Appeal therefore finds that the reasoning in the Contested Decision is appropriate to the act at issue, and explains in a clear manner the reasoning followed by the Agency for each information request.

117. The Board of Appeal will next address the Appellant's claim, essentially, that the Agency disregarded the comments the Appellant submitted in relation to the request for information on worker exposure and therefore infringed Article 51(5). The Board of Appeal observes that, at that stage of the decision-making process, the Appellant already had the possibility to comment earlier on the draft decision. Article 51(5) must be understood as giving the Appellant the opportunity to comment on any proposals for amendment to the draft decision and not once more on the draft decision itself. As the Appellant's comments on worker exposure assessment did not relate to the proposals for amendment of the draft decision the Agency was therefore justified in not considering those comments.

118. Having regard to all of the foregoing considerations, the Board of Appeal finds that none of the arguments put forward by the Appellant in support of the third plea is capable of establishing that the Agency breached its duty to state reasons. In these circumstances, the third plea relied on by the Appellants in support of their appeal must be rejected.

The Appellant's fourth plea alleging that the Contested Decision was adopted in breach of Article 25

Arguments of the Parties

119. In support of its fourth plea, the Appellant argues that the '*objective of avoidance of animal testing is a general principle of the REACH Regulation, and applies every step of the way to the activities undertaken in this context*'. It applies to both registrants and the Agency.

120. The Appellant claims that in the present case, when requesting the information specified in the Contested Decision, the Agency has not taken into account the need to avoid unnecessary animal tests.

121. The Agency contends that it fully adhered to the need for testing on vertebrate animals to be a last resort as stated in Article 25(1). It argues that the Board of Appeal's decision in case A-005-2011 does not remove the burden of proof from registrants and transfer it to the Agency when it comes to standard information requirements. Pursuant to substance evaluation, when a request is for a standard information requirement, the Agency does not bear the burden of demonstrating that such a request needs to be fulfilled by a test conducted on vertebrate animals.

122. Furthermore, the Agency argues that no study protocol or guideline is available that would allow the investigation of local respiratory effects without using vertebrate animals. As a result, the request for a 28-day RDT study by inhalation was the only possible outcome of the substance evaluation process in question.

Findings of the Board of Appeal

123. The Board of Appeal observes that, by claiming that the Agency has not, in the Contested Decision, taken into account the need to avoid animal tests, the Appellant essentially contends that the Agency breached Article 25(1). The Board of Appeal notes that, in support of its fourth plea, the Appellant does no more than raise a few general points without making detailed arguments as regards the circumstances of the case under review. The Appellant fails to explain how the Agency's actions in the present case actually result in a violation of Article 25(1). The Board of Appeal therefore finds it impossible to examine which of the Agency's actions in the present case, and how those actions, lead to the alleged infringement of Article 25(1), making it, as a result difficult for the Board of Appeal to exercise its power of review.

124. In any event, the Board of Appeal recalls that Article 25(1) provides that '*in order to avoid animal testing, testing on vertebrate animals for the purposes of [the REACH] Regulation shall be undertaken only as a last resort […]*'.

125. The Board of Appeal observes that the only test requiring the use of animals in the Contested Decision is the 28-day RTD study. The plea regarding Article 25(1) can only therefore apply to this test.

126. With regard to the 28-day RTD study, the Board of Appeal notes that the Agency concluded in the Contested Decision, without being contradicted by the Appellant on this point during the substance evaluation procedure, that '*no animal free tests exist to investigate the possible local respiratory effects after inhalation exposure*'. Furthermore, as explained at paragraph 97 above, no suitable non-animal alternative to the requested study has been identified.

127. The Board of Appeal finds therefore that the plea alleging that the Contested Decision was adopted in breach of Article 25(1) is unfounded and must be dismissed.

128. It follows from all the above considerations that the appeal must be dismissed in its entirety.

Refund of the appeal fee

129. 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.

130. As the Board of Appeal has decided the appeal in favour of the Agency in the present case the appeal fee shall not be refunded.

Effects of the Contested Decision

131. The Contested Decision, upheld in the present appeal proceedings, required the concerned registrants, including the Appellant, to submit the required information by 25 May 2015, that is 15 months from the date of that Decision. The Board of Appeal considers however that because of the duration of the present appeal proceedings and in light of the application of the suspensive effect as laid down in Article 91(2), the deadline set in the Contested Decision for the submission of the requested information should be interpreted as if it referred to 15 months from the date of the final decision of the Board of Appeal.

132. Consequently, the information required by the Contested Decision shall be submitted within 15 months 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 appeal fee shall not be refunded.**

3. **Decides that the information required by the Agency's Decision of 25 February 2014 on the substance evaluation of hexyl salicylate, notified to the Appellant through the annotation number SEV-D-2114273859-29-01/F and to other registrants of hexyl salicylate, as identified in the annex on page 15 of the Contested Decision, shall be submitted by 27 January 2017.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal