EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

23 September 2015

(Substance evaluation – Risk – Proportionality – Data gap – EOGRTS – Compliance check)

Case number	A-005-2014
Language of the case	English
Appellants	Akzo Nobel Industrial Chemicals GmbH, Germany Dow Deutschland Anlagengesellschaft mbH, Germany KEM ONE, France INEOS ChlorVinyls Ltd, United Kingdom Solvay Chimica Italia S.p.A., Italy Solvay Electrolyse France SAS, France
Representative	Jean-Philippe Montfort Mayer Brown Europe-Brussels LLP
Intervener	European Coalition to End Animal Experiments (hereinafter 'ECEAE'), United Kingdom
Contested Decision	Decision of 26 February 2014 on the substance evaluation of carbon tetrachloride 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 Appellants through the following annotation numbers: SEV-D-2114274040-63-01/F, SEV-D-2114274051-60-01/F, SEV-D-2114274042-59-01/F, SEV-D-2114274043-57-01/F, SEV-D-2114274049-45-01/F, and SEV-D-2114274050-62-01/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 Appellants lodged the present appeal at the Registry of the Board of Appeal in which they requested the Board of Appeal to annul the Contested Decision in its entirety and order the European Chemicals Agency (hereinafter the 'Agency') to refund the appeal fee.

Background to the dispute

2. 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 '*human health/CMR; Exposure/High exposure for workers, high aggregated tonnage*', carbon tetrachloride (hereinafter the 'Substance') was included in the Community rolling action plan (hereinafter the 'CoRAP') for substance evaluation in 2012 pursuant to Article 44(2) of the REACH Regulation (all references to Recitals, Titles, Articles, and Annexes hereinafter concern the REACH Regulation unless stated otherwise). The CoRAP was published on the website of the Agency on 29 February 2012. The evaluating Member State Competent Authority appointed was France (hereinafter the 'eMSCA').

3. At the time of the Contested Decision there were two full registrations of the Substance pursuant to Article 6, one at the 1 000 tonnes or more per year tonnage band and the other at the 10 to 100 tonnes per year tonnage band, five transported isolated intermediate registrations in accordance with Article 18 and one on-site isolated intermediate registration pursuant to Article 17.

4. The Substance is used as an intermediate in closed industrial processes, as an industrial process agent (solvent) in closed systems, and as a laboratory agent by professional workers.

5. Following an evaluation of the Substance, pursuant to Article 45(4), the eMSCA prepared a draft decision, pursuant to Article 46(1), requesting further information. The draft decision was submitted to the Agency on 28 February 2013. In the draft decision the Appellants were requested to provide a two-generation reproductive toxicity study (OECD test guideline (hereinafter 'OECD TG') 416). According to the draft decision sent to the Appellants on 4 April 2013 for comments pursuant to Article 50(1):

   '*The concern on the developmental and reproductive toxicity of [the Substance] could be partially answered by an OECD [TG] 421 study (reproductive/developmental toxicity screening test in rat) or an EOGRTS […]. However, only a two-generation reproduction toxicity study in rats is considered appropriate to sufficiently clarify the concern by providing information on*

   - *the integrity and performance of the male and female reproductive systems,*
   - *the effect on neonatal and postnatal developmental toxicity.*'

6. On 29 April 2013, the Appellants provided comments to the Agency on the draft decision.

7. The draft decision was modified by the eMSCA taking into account the comments of the Appellants. On 1 August 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 four MSCAs. One MSCA proposed rejecting the two-generation reproductive toxicity study as, based on available information, there was not a concern regarding reproductive toxicity. Other proposals for amendment suggested that the decision should request an extended one generation reproductive toxicity study (hereinafter 'EOGRTS') without the F2 (second filial) generation and with DIT/DNT (developmental immunotoxicity/developmental neurotoxicity) cohorts. Other proposals for amendment suggested specifying the most relevant route of administration for the study (oral or inhalation).

8. On 6 September 2013, the Agency notified the Appellants of the proposals for amendment to the draft decision and invited them, pursuant to Articles 52(2) and 51(5), to provide comments within 30 days.

9. The eMSCA reviewed the proposals for amendment and further amended the revised draft decision accordingly.

10. On 16 September 2013, the Agency referred the amended draft decision to the MSC.

11. On 6 October 2013, the Appellants provided comments on the proposals for amendment.

12. After discussions in the MSC meeting of 4 to 8 November 2013, at which representatives of the Appellants were present, a unanimous agreement of the MSC on the draft decision, as modified at the meeting, was reached on 7 November 2013.

13. The Contested Decision was adopted by the Agency on 26 February 2014 requesting the Appellants to submit information on an EOGRTS by inhalation (OECD TG 443) using the Substance by 26 May 2016. According to the Contested Decision, having taken the proposals for amendment and the Appellants' comments thereon into account, the draft decision was changed to request an EOGRTS by inhalation rather than a two-generation reproductive toxicity study. The Contested Decision states that '*DIT/DNT cohorts are considered to be included in the OECD [TG] 443 but can be omitted by the registrants by providing sufficient scientific justification*'.

14. According to the Contested Decision an EOGRTS is required:

'*… in order to enable the [eMSCA] to assess properties on reproduction*.

W*ithout the requested information it will not be possible to verify whether there remains an uncontrolled risk with the [S]ubstance that should be subject to further risk management measures*.

On the basis of available data, provided by registrants and found in the literature, no clear conclusions about the reproductive toxicity potential of the [Substance] can be made…'.

15. In addition to the Contested Decision, on 26 February 2014, two Agency Decisions were issued to clarify other concerns identified for the Substance. These Decisions were addressed only to certain of the Appellants in order to clarify concerns for the Substance stemming from their registrations. Both of these Decisions were intended to clarify exposure of workers to the Substance from non-intermediate use. One of the Decisions also required further information to clarify potential environmental exposure. The information requested in the two Decisions was to be provided by 26 May 2016. These two Decisions have not been contested.

Procedure before the Board of Appeal

16. On 26 May 2014, the Appellants lodged the present appeal at the Registry of the Board of Appeal.

17. On 1 and 2 July 2014 respectively, the French Republic and the Danish Environmental Protection Agency applied to intervene in the proceedings before the Board of Appeal in support of the Agency. By separate Decisions of 16 October 2014, the Board of Appeal, having heard the Parties, dismissed both applications to intervene due to the fact that they 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').

18. On 8 July 2014, ECEAE (hereinafter the 'Intervener') applied to intervene in the proceedings before the Board of Appeal in support of the Appellants. By Decision of 13 October 2014, the Board of Appeal, having heard the Parties, granted the Intervener's application to intervene.

19. On 30 July 2014, since the position of legally qualified member of the Board of Appeal was vacant and in order to achieve the full composition of the Board of Appeal, the Chairman of the Board of Appeal, 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.

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

21. On 30 September 2014, the Appellants submitted their observations on the Defence.

22. On 11 November 2014, the Agency submitted its observations on the Appellants' observations on the Defence.

23. On 15 December 2014, the Intervener submitted its statement in intervention.

24. On 4 and 5 February 2015 respectively, the Appellants and the Agency submitted their observations on the Intervener's statement in intervention.

25. On 4 March 2015, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 17 March 2015, the Appellants requested that a hearing be held. On 18 March 2015, the Agency informed the Board of Appeal that it did not request a hearing. In view of the Appellants' request, and pursuant to Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 20 May 2015. At the hearing, the Parties and the Intervener made oral presentations and responded to questions from the Board of Appeal.

Reasons

26. In support of the form of order sought, the Appellants claim, firstly, that the Contested Decision breaches the principle of proportionality. In particular, the Appellants argue that the study requested by the Agency is not necessary to complete the evaluation of the Substance to determine whether the Substance constitutes a risk to human health or the environment. The Appellants also argue that the Agency did not demonstrate

that the requested study is adequate to achieve the objectives pursued. In addition, the Appellants argue that the requested study is not the least onerous measure to attain the objective pursued.

27. The Appellants claim, secondly, that the Contested Decision breaches Article 13(3) as the requested study has not yet been introduced into Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1), nor is it an international test method recognised by the Commission or the Agency as being appropriate.

28. The Appellants claim, thirdly, that the Contested Decision breaches Article 25(1) as the Agency did not ensure that testing on vertebrate animals is undertaken only as a last resort. In addition, the Appellants claim that, if vertebrate animal testing is needed in this case, the Agency failed to ensure that the fewest number of animals possible are used to satisfy the objective pursued as required by Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

29. The Appellants claim, fourthly, that the Agency infringed its duty to state reasons with regards to why it changed its request from a two-generation reproductive toxicity study in the draft decision to an EOGRTS in the final decision.

30. The Appellants claim, fifthly, that the Agency breached the Appellants' right to be heard as the Appellants were not given the possibility to review and comment on certain data submitted by the eMSCA shortly before the MSC meeting at which the Contested Decision was agreed.

31. The Appellants claim, sixthly, that the Contested Decision breaches the principle of legal certainty and non-retroactivity as they were only notified of the deadline after which updates of their registration dossier would not be taken into account after that deadline had passed.

The Appellants' first plea alleging a breach of the principle of proportionality

Arguments of the Parties and the Intervener

32. According to the Appellants, no additional information is needed to conclude on the reproductive toxicity of the Substance and therefore an EOGRTS is not necessary to determine whether the Substance constitutes a risk to human health or the environment.

33. In particular, the Appellants argue that adequate data exists demonstrating that reproductive toxicity only occurs at very high levels of exposure and that liver toxicity is always observed at much lower levels of exposure. The Appellants add that no observed adverse effect levels (hereinafter 'NOAELs') for reproductive toxicity already exist and that sufficient regulatory measures are already in place to ensure the protection of human health. According to the Appellants, the derived no-effect level (hereinafter 'DNEL') derived from available studies are higher than the DNEL derived for systemic (liver) toxicity. As a result, the DNEL based on systemic toxicity will also be sufficient to protect against reproductive effects. The Appellants argue that it is very unlikely that performing an EOGRTS would lead to a lower NOAEL (and therefore a lower DNEL and consequently further risk management measures).

34. The Appellants claim that the Agency failed to take into account all the relevant facts and circumstances when assessing the necessity of adopting a measure in the present case. In particular, the Appellants argue that the Agency failed to take into account the following:

    - The effects on reproduction, in the studies relied on by the Agency to justify the concern, are only seen at very high levels of exposure and use doses several times higher than the NOAEL for liver toxicity. The Agency also failed to take into account the existing Occupational Exposure Limit (hereinafter 'OEL') for the Substance based on a NOAEC (No Observed Adverse Effect Concentration) for the liver established via inhalation studies,
    - Exposure to the Substance is very limited and controlled in a way which effectively prevents emissions to the environment as well as worker exposure. A concern regarding effects on fertility after repeated exposure to the Substance is therefore not justified,
    - The Substance is already very highly controlled and there should be no consumer use and no exposure to the general population. Potential exposure to workers is already well managed by specific risk management measures aimed at keeping exposure to the Substance well below levels inducing systemic toxicity, and
    - Restrictions apply that limit the Substance's use except as an intermediate and industrial processing agent. Volumes permitted for non-intermediate use are fixed each year by the competent authorities.

35. The Appellants also claim that since the Agency has requested further information on exposure from certain registrants in two separate Decisions it does not make any sense to anticipate the outcome of those Decisions by requesting an EOGRTS to be conducted before the results are known.

36. The Appellants also claim that the Agency did not demonstrate that the EOGRTS is adequate to achieve the objective pursued by the Contested Decision. In particular, the Appellants argue that the Agency did not take into consideration the following:

    - The EOGRTS is not yet validated at European Union and international level and, at the time the Contested Decision was adopted, the European Union authorities acknowledged that there were remaining scientific uncertainties as to whether, and in which conditions, an EOGRTS without the F2 generation and DNT/DIT cohorts would be considered acceptable,
    - The results of an EOGRTS may be contested if the Appellants perform the EOGRTS without the F2 generation and DNT/DIT cohorts as they would have to provide '*sufficient scientific justification*' for doing so which may be rejected. The Agency therefore failed to consider whether the results of an EOGRTS, which is currently an unprecedented and non-validated study, might face regulatory obstacles, and
    - An EOGRTS, if feasible, may not produce meaningful results, in particular because the current design of the test method would not allow the Appellants to conduct an adequate assessment of the fertility parameters which according to the Contested Decision need to be assessed.

37. The Appellants also claim that the Agency failed to adopt the least onerous measure. In particular, the Appellants argue that the EOGRTS is '*overkill*' in terms of the number of animals sacrificed and the costs, and furthermore the remaining uncertainties in conducting an EOGRTS exceed the potential benefits.

38. According to the Appellants, a less onerous measure would be an OECD TG 421 screening test, slightly adapted in order to extend the premating period and to adjust the observations to address the specific parameters pertaining to fertility. The Appellants claim that that information would resolve any supposedly remaining concerns, as addressed in the Contested Decision, while reducing drastically the number of animals sacrificed and avoiding any uncertainty linked to test design, validation and acceptance of an EOGRTS as an appropriate method under the REACH Regulation.

39. In addition, the Appellants claim that it became evident during the present proceedings that the concern that led to the Contested Decision was the fact that the registration dossier prepared by one of the Appellants for the Substance did not contain a test for the reproductive toxicity endpoint but rather included a waiver that the Agency considers inadequate. In these circumstances the Appellants consider that the Agency should have used the compliance check procedure under Article 41 to assess the waiver and, if necessary, request the relevant registrant, rather than all the Appellants, to conduct the missing test.

40. The Appellants state that it is not sufficient for the Agency to refer to the absence of data and/or the inadequacy of a waiver to justify a substance evaluation decision without further establishing that the concern is such that it justifies involving all the registrants of the Substance.

41. The Agency claims that the objective pursued by substance evaluation is to clarify the risks that a substance may pose to human health or the environment where there are concerns for such risks. According to the Agency, such concerns exist where the standard information requirements set out in Annexes VII to X are not available in the registration dossier and these standard information requirements are relevant for the scope of the substance evaluation in question. The Agency states that the two-generation reproductive toxicity study is a standard information requirement for one of the Appellants.

42. The Agency claims that a registrant of the Substance at the 1 000 tonnes or more per year tonnage band (and also one of the Appellants) failed to demonstrate that the conditions for adaptation of the standard testing regime requirement for a two-generation reproductive toxicity study, pursuant to Section 3 of Annex XI, have been met. The Agency adds that the first draft decision, received by the Appellants for commenting pursuant to Article 50(1), explained the inadequacy of the proposed adaptation.

43. The Agency argues that, pursuant to Article 46, the Agency can require information that goes beyond the applicable standard information requirements for a substance. According to the Agency, there is no requirement to perform substance evaluation only after a registration dossier has been assessed to be compliant under the compliance check procedure. According to the Agency, this ensures that the substance evaluation process is not delayed by first having to ensure full compliance of individual registration dossiers. Furthermore, according to the Agency, substance evaluation decisions can request alterations to recognised test methods. Such alterations can require examination of parameters which do not need to be examined to meet standard information requirements. The Agency claims that substance evaluation decisions can therefore be a better means to ensure that the generation of information is tailored to real information needs.

44. The Agency claims that in the present case the concern for reproductive toxicity was triggered by the studies referred to in the Contested Decision. The Agency adds that these studies raised concerns specifically due to the fact that testicular atrophy, abnormality in the process of spermatogenesis, inhibition of oestrous rhythm and weight and vascularisation decreases of ovary and uterus were observed after exposure to the Substance. The Agency adds that the studies identified were relevant despite the fact that in some of the studies the Substance was administered intraperitoneally and/or the doses used were high. The Agency claims that the available information does not support the Appellants' arguments that reproductive toxicity only occurs at doses that already cause systemic toxicity.

45. The Agency states that '*the concern for toxicity is based on the two pillars of hazard information necessary and exposure*'. The Agency adds that in this case '*the hazard data is required by means of the EOGRTS. Exposure information is being asked from the Appellants with respective non-intermediate uses*'.

46. The Agency argues that, with regards to exposure to the Substance, as all the Appellants did not have to submit a chemical safety report, the Agency does not hold data on the estimated exposure for all of the uses in all registrations. The Agency also argues that the available information on exposure to the Substance supports the finding that the applicable requirement of Section 8.7.3 of Annex X, a two-generation reproductive toxicity study, cannot be waived pursuant to Section 3 of Annex XI.

47. The Agency claims that the available data clearly shows that workers are exposed to the Substance. The Agency states that the fact that the Substance has been registered for uses other than as an intermediate under strictly controlled conditions demonstrates that there is possible exposure. The Agency argues that the Contested Decision refers to a risk characterisation ratio (hereinafter 'RCR') for some uses that are close to one, indicating a potential risk. According to the Agency, with the results of the EOGRTS requested in the Contested Decision the RCR may well go above one thereby indicating a potentially dangerous exposure and possibly indicating an uncontrolled risk.

48. The Agency claims that an EOGRTS is adequate to achieve the objective pursued and this was carefully considered during the decision-making process. For example, the Agency states that due to the very high vapour pressure of the Substance the MSC agreed that testing should be done by the inhalation route.

49. The Agency also states that there is no reason to suggest that the results of an EOGRTS may be challenged. In particular, according to the Agency, the Appellants do not have to scientifically justify why they do not proceed to test the F2 generation as it has not been specifically requested. The omission of the DNT/DIT cohorts would however have to be justified by the Appellants.

50. In addition, the Agency claims that an EOGRTS is the least onerous measure to clarify the concern identified. The Agency argues that the Appellants' suggestion that an OECD TG 421 screening study would have been the least onerous and adequate measure is unfounded, in particular because according to the test guideline the test '*…does not provide complete information on all aspects of reproduction and development*'. The Agency also claims that the OECD TG 421 screening study is not adequate to clarify the concern even if modified as suggested by the Appellants. The Agency adds that a pre-natal developmental toxicity study in the first species is - regardless of the outcome of a screening study - a standard information requirement under Annex IX. In addition, the two-generation reproductive toxicity study is a

standard information requirement at the Annex IX and X levels. According to the Agency, in most cases, where the standard information requirements for reproductive toxicity apply, animals can be spared by directly carrying out the two-generation reproductive toxicity study and thereby waiving the requirement for the screening study in accordance with the fourth indent of Column 2 of Annex IX, Section 8.7.1. The Agency claims that since the screening study would not be expected to provide the data considered necessary to clarify the concern, the Agency would require a further study later anyway.

51. The Intervener argues that the Contested Decision is disproportionate in particular because:

- The Agency has identified an illegitimate objective, namely the need to fill an alleged data gap under Annex X, and is unclear about the precise objectives pursued or how the mandated study could meet that objective,
- Under the necessity part of the proportionality principle, since the Contested Decision concerns substance evaluation and not dossier evaluation, the Agency has had regard to irrelevant considerations, such as whether the Appellants fall within the conditions for adaptation under Annex XI,
- The Agency has failed to have regard to considerations such as the consolidated DNEL being unlikely to be lower than the hepatotoxicity DNEL, the already strict risk management measures applied to the Substance, and the practical difficulties in performing an EOGRTS by inhalation, and
- The Agency has not considered the step-wise approach, in particular awaiting the results of the information requested by the additional Agency Decisions on exposure or requiring a screening study to be carried out first.

Findings of the Board of Appeal

52. At the outset, 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-005-2011, *Honeywell Belgium N.V.,* Decision of the Board of Appeal of 29 April 2013, paragraphs 115 to 117).

53. With regards to judicial review of the conditions referred to in the previous paragraph, the European Union Courts have highlighted that the Agency has a broad discretion in a sphere which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. According to the European Union Courts, the legality of a measure contested before it and adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the legislature is seeking to pursue (see, for example, Case T-96/10, *Rütgers Germany GmbH and Others* v *ECHA*, EU:T:2013:109, paragraph 134).

54. However, in relation to the '*manifestly inappropriate*' criterion set by the European Union Courts when conducting a judicial review of the proportionality of a measure, the Board of Appeal underlines the clear differences between itself and the European

Union Courts. In particular, the latter refrain from substituting their own assessment for that of the European Union institution whose decision is being reviewed (see by analogy Case C-525/04 P, *Spain* v *Commission*, EU:C:2007:698, paragraphs 60 and 61). However, under Article 93(3), the Board of Appeal '*may exercise any power which lies within the competence of the Agency […]*'. Thus, the Board of Appeal can inter alia replace a decision under appeal with a different decision. Moreover, in conducting its administrative review of Agency decisions, the Board of Appeal possesses certain technical and scientific expertise which allows it to enter further into the technical assessment made by the Agency than would be possible by the European Union Courts. As a result, when examining whether a decision adopted by the Agency is proportionate, the Board of Appeal considers that it should not be limited by the need to establish that the decision is '*manifestly'* inappropriate to the objective pursued.

55. The Board of Appeal firstly observes that the process for the registration of substances, set out in Title II, is designed to generate a 'base set' of information from the 'standard information requirements' set out in the Annexes to the REACH Regulation and that, as explained in Recital 19, this data should be used by registrants *'…to assess the risks related to these substances and to develop and recommend appropriate risk management measures'*. Compliance with the registration requirements is assessed by the Agency through a compliance check as part of dossier evaluation, as set out in Chapter 1 of Title VI.

56. The Board of Appeal secondly observes that the objective of substance evaluation under Chapter 2 of Title VI is referred to in several of the Recitals. For example, Recital 20 explains that the evaluation provisions allow *'…for generation of more information on the properties of substances'* and that:

'*…If the Agency in cooperation with the Member States considers that there are grounds for considering that a substance constitutes a risk to human health or the environment, the Agency should, after having included the substance in the [CoRAP] for substance evaluation, relying on the competent authorities of the Member States, ensure that this substance is evaluated.*'

57. This is repeated in Article 44(2) which provides:

'*…Substances shall be included [in the CoRAP] if there are grounds for considering…that a given substance constitutes a risk to human health or the environment…*'.

58. More importantly in the context of a substance evaluation decision, Recital 66 states that:

'*The Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to human health or the environment…*'.

59. In view of the above, the Board of Appeal considers that, under substance evaluation, in order to request additional information the Agency must be able to, firstly, demonstrate that there is a potential risk to human health or the environment. The Board of Appeal recognises that, with the objective in the REACH Regulation regarding protection of human health and the environment in mind, proof of a real risk is too high a threshold to meet. Nevertheless, the Agency must be able to demonstrate the presence of a potential risk.

60. Furthermore, 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 only theoretically. The Board of Appeal also observes that the primary objective in the REACH Regulation of the protection of human health and the environment would not be served by requests for the generation of information that would not meet '*real information needs*'. Additionally, the competitiveness of European Union industry, another objective of the REACH Regulation, although subordinate to the protection of human health and the environment, would be compromised by incurring costs for tests which do not satisfy '*real information needs*'. The Agency must therefore be able to demonstrate, secondly, that the potential risk identified needs to be clarified. Thirdly, the Agency must be able to demonstrate that the information requested has a realistic possibility of leading to improved risk management measures.

61. The Board of Appeal will firstly examine therefore whether the Agency has identified a potential risk. The Board of Appeal observes that the identification of a potential risk is based on a combination of hazard and exposure information. In this respect, the Agency claimed during the present proceedings that additional information on the potential hazard will be acquired by means of an EOGRTS and on the potential exposure from information provided by certain registrants by way of two separate Agency Decisions (see paragraph 15 above). According to the Agency, these two elements will clarify whether there is a concern for reproductive toxicity from the use of the Substance, in other words, whether there is a risk that needs to be further managed.

62. In relation to potential exposure to the Substance, the Board of Appeal observes that the Substance is very highly regulated. According to the Appellants, the Substance is restricted under Annex XVII, Regulation (EC) No 1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1) which prohibits its use except as an intermediate and industrial processing agent, and by OELs which have to be observed. As a result of these restrictions, there is no suspected consumer, or widespread, exposure to the Substance. According to the information currently available to the Board of Appeal, the only possible exposure is to workers. The risk posed by the Substance to workers is currently managed on the basis of a DNEL derived from information on systemic liver toxicity. There are also strict safe handling measures in place to protect workers, such as the requirement to wear protective equipment and appropriate exhaust ventilation at facilities.

63. The Appellants claim that, based on the current state of scientific knowledge, any reproductive toxicity would only arise at levels of exposure well above the current DNEL. According to the Appellants, the current DNEL set for systemic liver toxicity would therefore protect not only against liver damage but also against reproductive toxicity, the concern identified by the Agency in the Contested Decision. The Appellants therefore argue that an EOGRTS, as requested by the Contested Decision, would not be of any practical benefit. In other words, according to the Appellants, it is unlikely that the new information would lead to a change in the DNEL derived from evidence regarding liver toxicity.

64. The Agency argues that there is still uncertainty over the precise dosage which would trigger reproductive toxicity and it cannot be certain that the existing DNEL would be sufficient for risk management purposes. Furthermore, the Agency argues that some workers are exposed to the Substance and that the risk they face may not be adequately managed. The Agency therefore considers that it is possible that the requested EOGRTS might lead to a revised DNEL and/or other revisions to existing risk management measures.

65. The Board of Appeal finds that the eMSCA and the Agency, in the decision-making process, the Contested Decision and during these proceedings, have not rebutted, to the satisfaction of the Board of Appeal, the Appellants' assertion that the existing DNEL (based on systemic liver toxicity) ensures that there will be no exposure to the Substance at levels at which there is a realistic possibility (based on the evidence available) of reproductive toxicity. At the current time, the Agency, whilst demonstrating a degree of uncertainty, has not been able to demonstrate that there is a realistic possibility of exposure at levels which may cause reproductive toxicity. Furthermore, no evidence has been presented to the Board of Appeal which would support the conclusion that the current risk management measures are inadequate to address the concerns for systemic liver toxicity and therefore for reproductive toxicity.

66. The Agency further argues, as stated in the Contested Decision, that '*[a]s some RCR with the proposed DNEL by registrants are close to 1, the use of a lower (FR-CA) DNEL would result to RCR superior to 1. In this context refinement of exposure scenarios are necessary*'. The Board of Appeal finds the Agency's arguments (see paragraph 47 above) in relation to RCRs close to 1 unconvincing. The Board of Appeal observes that it is necessary for RCRs to be below 1 in order to demonstrate safe use. However, just because a RCR is close to 1 does not mean that the exposure in practice is close to that which could lead to effects on health. Sometimes RCRs are close to 1 because the registrant concerned wants to explore the limits of exposure whilst putting far more protective measures in place, for example, shorter periods of exposure, more effective extraction systems, or better protective equipment. Furthermore, establishing a RCR close to 1 can serve as a warning that further safety measures may need to be adopted and actually benefit the protection of human health. In the present case the Appellants explained that they had established alternative RCRs below 0.5 to help identify how workers can work safely and well below the RCR close to 1 (0.98). The Agency needs to be able to demonstrate that the exposure is such that there is potentially a concern for human health. The Board of Appeal observes that the objective of the two other Agency Decisions (see paragraph 15 above) is to do this. The Board of Appeal fully recognises that in some chemical safety reports registrants may have made certain assumptions, for example modifying safety factors and identifying unrealistic protective measures, to ensure a RCR is below 1. In such cases the Agency may be able to justify why additional information is needed pursuant to a substance evaluation. In this particular case, however, the Agency has not justified why a RCR close to 1 in itself justifies a request for an EOGRTS to be conducted.

67. As stated above in paragraph 15, two other substance evaluation Decisions have been sent to individual registrants of the Substance with the aim of gathering further exposure information for specific uses. In one of those Decisions the registrant is requested to:

'*…submit the following information:*

- *Further details of monitoring information already presented in the registration dossier. Detailed protocols, operational conditions, and description of tasks used to*

measure the exposure of workers, for all tasks and personal protective equipment worn during these tasks. The raw data of results and the analysis methods used to measurement shall also be submitted.

- *Detailed specifications of the personal protective equipment shall be provided for each exposure scenario*.'

68. The Board of Appeal notes that the information submitted in response to these Decisions may indicate that there is potentially a level of worker exposure which could require additional risk management measures. However, at the present time, the Board of Appeal has no evidence that this information is available to the Agency and therefore the Agency's conclusion regarding worker exposure is premature.

69. The Board of Appeal will next examine whether the Agency has identified a hazard concern that could help justify a request for additional information on reproductive toxicity through an EOGRTS pursuant to a substance evaluation.

70. The Board of Appeal observes that the Agency concluded in the Contested Decision that there are some uncertainties regarding the reproductive toxicity of the Substance. The Agency presented evidence in the Contested Decision from test results indicating that there was a concern with regard to reproductive toxicity. The Appellants have pointed out that there are also other test results which appear to show no concern for reproductive toxicity or only effects at high doses and, in particular, at higher levels of exposure than can be reasonably foreseen. The Appellants have also argued that the Agency's arguments do not stand up to scrutiny as some of the tests are old and insufficiently described, others do not follow international test guidelines, and others use unusual routes of exposure, such as via the peritoneum. Whilst these arguments do not in themselves render the results on which the Agency depends invalid, the Board of Appeal considers that the Agency's evidence supporting a concern for reproductive toxicity is nevertheless weak, in particular at doses at which workers can reasonably be expected to be exposed. This is despite the many studies that have been identified and examined by both the Appellants and the Agency. The Board of Appeal further notes that there is no indication that the Substance causes reproductive toxicity at dose levels that would not be associated with significant systemic toxicity.

71. With regard to the need for the Agency to demonstrate that the requested EOGRTS has a realistic possibility of leading to improved risk management measures, in light of the findings above, the Board of Appeal concludes that the eMSCA and the Agency, in the decision-making process, the Contested Decision and during these proceedings, have not demonstrated that the risk management measures already in place, consequent to the various regulatory requirements and the DNEL developed as a result of systemic liver toxicity, will not ensure the protection of workers from harm caused by possible exposure to the Substance.

72. In view of paragraphs 61 to 71 above, the Board of Appeal finds that, in this particular case, the Agency has not demonstrated that there is a potential risk that needs to be clarified and that the requested information has a realistic possibility of leading to improved risk management measures. In other words, the Agency has not demonstrated that the requested information is necessary to meet real information needs regarding the protection of human health and the environment.

73. The Board of Appeal considers that under the substance evaluation procedure greater clarity regarding the potential risks to human health and the environment are required in order to substantiate a request for further information. The Agency must be able to demonstrate that there is a potential risk, that this risk needs to be clarified, and that

the requested information has a realistic possibility of leading to improved risk management measures. If these conditions cannot be met the information requested would not meet real information needs for the protection of human health and the environment pursuant to substance evaluation.

74. During the present proceedings the Appellants claimed that the concern identified by the Agency to justify requesting the EOGRTS was the fact that the registration dossier prepared by one of the Appellants for the Substance did not contain the standard information required in Section 8.7.3 of Annex X but rather contained a waiver that the Agency considered inadequate. The Agency confirmed in its Defence that it considers '*there is a concern when the standard information requirements which are applicable to submitted registrations are not available in case these standard information requirements are relevant for the scope of the substance evaluation process*'.

75. The Board of Appeal finds however that a perceived gap in the standard information requirements cannot, in itself, justify a request to fill such a data gap pursuant to substance evaluation. A data gap does not constitute on its own evidence of a potential risk for human health or the environment. In other words, the Agency's conclusion that the failure of one of the Appellants to provide some of the standard information in their registration dossier cannot, on its own, justify a request for that information pursuant to substance evaluation.

76. The Board of Appeal observes that the compliance check procedure set out in Article 41 has been put in place to evaluate whether registration dossiers comply with the relevant information requirements. If, when carrying out the compliance check of a registration dossier under Article 41, the Agency considers that there is a data gap and as a result the registration dossier does not comply with the standard information requirements, the registrant will be requested to provide the information that is considered to be missing. This is clear, for example, from Article 41(1) and (3) which provides that:

'*1. The Agency may examine any registration in order to verify any of the following:*

(a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;

(b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;

(c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;

(d) that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.

[…]

3. On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements […].'

77. The Board of Appeal observes that the objectives of dossier and substance evaluation, as described in paragraphs 56 to 60 above, are therefore different. Furthermore, whilst the REACH Regulation contains no explicit requirement that dossier evaluation should precede substance evaluation, the Board of Appeal observes that there are a number of indications in the REACH Regulation which suggest that the normal course of action should be for the Agency to carry out a compliance check prior to the performance of a substance evaluation.

78. For example, Article 47(1) states that '*[a]n evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation under this Title…*'. The Board of Appeal also considers that pursuing dossier evaluation prior to substance evaluation should ensure that the latter evaluation is carried out on the basis of a more 'complete' set of data. Evaluation of a 'complete' data set may allow it to be concluded, for example, that the Substance does not constitute a risk and that no further data is required.

79. Similarly, Article 42(2) states that the MSCAs shall use the information obtained from a dossier evaluation, inter alia, to prioritise a substance for evaluation. Likewise Article 44(2) provides that substances shall be included on the CoRAP '*…if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment.*' These provisions suggest that a compliance check is foreseen in some cases even before the substance is placed on the CoRAP and therefore prior to the substance evaluation process.

80. The Board of Appeal notes that, pursuant to Article 41(5), the Agency is required to perform a compliance check on at least 5% of the total number of dossiers received for each tonnage band. Whilst the Agency is not therefore required to perform a compliance check on all registration dossiers, the Board of Appeal observes that, according to Article 41(5)(c), one of the prioritisation criteria for selecting dossiers for a compliance check is that '*the dossier is for a substance listed in the [CoRAP] referred to in Article 44(2).'* This provision again suggests that a compliance check should normally be performed by the Agency before the substance evaluation process is initiated.

81. The Board of Appeal observes that in the present case one of the Appellants, and the only registrant of the Substance at 1 000 tonnes or more per year, had proposed a waiver in its registration dossier as a means to fill the information requirement set out in Section 8.7.3 of Annex X. The Board of Appeal observes that, under the compliance check procedure, and in particular as set out in Article 41(1)(b), adaptations should ordinarily be considered in the context of a compliance check. The Board of Appeal also notes that the second paragraph of the introduction to Annex XI, states that '*[u]nder dossier evaluation the Agency may assess these adaptations to the standard testing regime*'. The Board of Appeal considers therefore that a conclusion regarding the adequacy of a waiving argument should ordinarily be reached under the compliance check procedure as this offers procedural safeguards to the registrant(s) concerned. For example, the possibility to provide observations on the draft decision and any findings dismissing the proposed waiver. In order to reject the waiving arguments the Agency would have to decide, and justify accordingly, whether those waiving arguments were adequate. The Agency has not however in the present case taken a decision on the adequacy of the waiving arguments pursuant to dossier evaluation.

82. The Board of Appeal also finds that in the Contested Decision, whilst referring to the validity of a study submitted in the registration dossier of one of the Appellants, the Agency did not take a formal decision on the adequacy of the waiving arguments pursuant to substance evaluation. The Board of Appeal considers that the fact that the Agency acknowledged the waiver in, for example, the draft decision of 4 April 2013 and provided certain arguments as to why the existing data is insufficient to conclude on the alleged hazard, is not sufficient in this respect.

83. The Board of Appeal considers therefore that it is not possible for the Agency to conclude, in the absence of a decision rejecting the waiving arguments, that the endpoint for Section 8.7.3 of Annex X has not been filled by one of the Appellants in this case.

84. Moreover, the Board of Appeal notes that an adaptation is specific to a registration and cannot therefore be used as an argument, on its own, for an information request imposed on several registrants pursuant to substance evaluation. It is not proportionate for a waiving argument by one registrant to form the basis for a substance evaluation decision, with the associated consequences for cost and enforcement, imposed on other registrants.

85. Importantly, the Board of Appeal also observes that the thresholds for registration purposes and the corresponding data requirements have been established by the legislator taking into account, amongst other things, the cost of generating data, the requirement for data and cost sharing, and the tonnage of the substance manufactured in, or imported into, the European Union. This can be deduced from Article 12 which sets out the minimum information to be submitted depending on the tonnage of the substance manufactured or imported into the European Union.

86. The Board of Appeal considers that if data gaps in registration dossiers could be filled through substance evaluation and directed at several registrants of a substance, regardless of the tonnage registered and the type of registration made, with the associated consequences for cost sharing, this could undermine the balance achieved in the legislation, for example between cost and information. Filling a standard information requirement through substance evaluation could lead to significant costs for low tonnage and intermediate registrants who would not be exposed to such costs if the standard information had been provided through a registration by a higher volume registrant. The Agency should not therefore without clear justification, in effect, extend the standard information requirements.

87. Nonetheless, the Board of Appeal observes that in addition to requiring information that goes beyond the applicable standard information requirements the standard information requirements set out in Annexes VII to X may, in certain circumstances, be requested under substance evaluation. This can be deduced from Article 46(1) which states that:

    '*If the competent authority considers that further information is required, including, if appropriate information not required in Annexes VII to X, it shall prepare a draft decision…*'.

88. The use of '*including*' in Article 46(1) indicates that a decision on substance evaluation can also request standard information. For example, the Agency could potentially request information that is standard at the highest tonnage band for a substance that has not been registered at that tonnage band or for a substance that has been registered at the highest tonnage band but the relevant test results were not included as the information requirement was successfully waived in a registration dossier. The

Board of Appeal also finds that under substance evaluation it may be appropriate to make alterations to recognised test methods, for example, the examination of parameters which do not need to be examined to meet standard information requirements. This helps ensure that information generated pursuant to a substance evaluation decision meets real information needs. Article 46(1) cannot, however, be read as a justification, in itself, for the Agency proceeding directly to substance evaluation without first conducting a compliance check pursuant to Article 41. In addition, Article 46(1) cannot be used as a justification, on its own, for imposing a request for standard information on all registrants of a substance under substance evaluation.

89. The Board of Appeal considers further that in the present case pursuing the compliance check procedure prior to substance evaluation would not have had adverse effects on the protection of human health and the environment. In particular, if a compliance check had been conducted in relation to the registrant registering at the 1 000 tonnes per year or more tonnage band and the waiving arguments set out in the registration dossier had been rejected by the Agency then testing could have been required through an Agency decision requiring the registrant to fulfil the standard information requirements.

90. As a result, the Board of Appeal finds that the substance evaluation procedure should not, ordinarily, be used in place of a compliance check to fill data gaps. The Board of Appeal considers, however, that the Agency may be able to provide sufficient reasoning to justify in certain cases, in light of the objectives of the REACH Regulation and substance evaluation and in particular the protection of human health and the environment, requesting information that should have, ordinarily, been requested following a compliance check procedure as set out in Article 41. For example, if the Agency can show that there is an immediate, relevant and real concern for human health or the environment from the use of a substance it may be appropriate to request the relevant effect data and/or information on exposure under the substance evaluation procedure rather than waiting for a compliance check to be conducted, and a decision implemented, ahead of a substance evaluation.

91. The Board of Appeal also considers that in the present case the Agency would have to adequately justify why it considers that it is appropriate to require under substance evaluation information that is standard for one of the registrants and why a substance evaluation decision requests that information from registrants which would have not been required to provide the information if it had been requested following a compliance check.

92. In the present case the Board of Appeal finds that neither the Contested Decision, nor the submissions in the present proceedings, provides sufficient justification as to why standard information on reproductive toxicity was requested from all of the Appellants or why the request for information was made pursuant to substance evaluation rather than a compliance check under the dossier evaluation procedure.

93. In view of all the above, the Board of Appeal finds that the Contested Decision is disproportionate on the grounds that an EOGRTS is not, based on the Contested Decision and the submissions in the present proceedings, necessary to clarify a risk to human health or the environment. In addition, the Agency has not adequately justified requesting information that was standard for one registrant from all the Appellants under the substance evaluation procedure. The Contested Decision must therefore be annulled and the case remitted to the Agency for further action.

Other pleas raised by the Appellants

94. As the Board of Appeal has found in favour of the Appellants it is not necessary for the purposes of the present appeal to consider the Appellants' additional pleas set out in paragraphs 26 to 31 above.

Refund of the appeal fee

95. 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.

96. As the Board of Appeal has decided the appeal in favour of the Appellants in the present case, the appeal fee shall be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Agency's Decision of 26 February 2014 on the substance evaluation of carbon tetrachloride notified to the Appellants through the annotation numbers SEV-D-2114274040-63-01/F, SEV-D-2114274051-60-01/F, SEV-D-2114274042-59-01/F, SEV-D-2114274043-57-01/F, SEV-D-2114274049-45-01/F, and SEV-D-2114274050-62-01/F.**

2. **Remits the case to the competent body of the Agency for re-evaluation.**

3. **Orders the refund of the appeal fee.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal