EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

25 September 2018

(Substance evaluation – Dossier Evaluation – Compliance check – Choice of procedure – Procedural rights – Extended one-generation reproductive toxicity study (EOGRTS))

Case number	A-007-2017
Language of the case	English
Appellant	Infineum UK Ltd, United Kingdom
Representatives	Jean-Philippe Montfort and Thomas Delille, Mayer Brown Europe-Brussels LLP, Belgium
Interveners	(I) SI Group-UK Ltd, United Kingdom, and Oxiris Chemicals S.A, Spain Represented by: Claudio Mereu and Maud Grunchard Fieldfisher (Belgium) LLP, Belgium (II) The Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management (BMLFUW), Austria
Contested Decision	Decision of 23 March 2017 on the substance evaluation of 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol adopted by the European Chemicals Agency pursuant to Article 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation')

THE BOARD OF APPEAL

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

Acting as Registrar: Marc Goodacre

gives the following

Decision

Background to the dispute

1. The Appellant registered 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol (EC No 204-279-1, CAS No 118-82-1; the 'Substance') at the 10 to 100 tonnes per year tonnage band. The joint Interveners, SI Group-UK and Oxiris Chemicals, registered the Substance at the 100 to 1 000 tonnes per year tonnage band. There were no registrations at the 1 000 tonnes or more per year tonnage band.

2. The Substance was included in the Community rolling action plan ('CoRAP') for substance evaluation in 2014. This was on the basis of an opinion of the Member State Committee (the 'MSC') and due to initial grounds for concern relating to '*environment/suspected PBT/vPvB, potential endocrine disruptor, suspected CMR, suspected sensitiser*, *exposure/wide dispersive use, consumer use, exposure of workers, exposure of environment*'. The CoRAP was published on the website of the European Chemicals Agency (the 'Agency') on 26 March 2014. The Competent Authority of Austria was appointed as the evaluating Member State Competent Authority (the 'eMSCA') for the Substance.

3. According to the Contested Decision, '*[i]n the course of the evaluation, the [eMSCA] identified additional concerns regarding environment/terrestrial toxicity and soil toxicity*'.

4. On 13 March 2015, Commission Regulation (EU) 2015/282[1] entered into force. That Regulation introduced the extended one-generation reproductive toxicity study ('EOGRTS') into Annexes VIII, IX and X to the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise). Those Annexes set out the registration requirements for substances manufactured or imported in quantities of 10 tonnes or more (Annex VIII), 100 tonnes or more (Annex IX) and 1 000 tonnes or more (Annex X) respectively.

5. Following an evaluation of the Substance pursuant to Article 45(4), the eMSCA concluded that further information was required in order to assess '*suspected CMR, Potential endocrine disruptor, Environment/Suspected PBT/vPvB, Environment/ terrestrial toxicity and soil toxicity*' concerns. The eMSCA prepared a draft decision pursuant to Article 46(1) which was submitted to the Agency on 26 March 2015. The draft decision contained a number of information requirements including:

   '*[EOGRTS] in rats, oral route, with the DNT and DIT cohort and an extended pre-mating period of 10 weeks (test method: OECD [TG] 443) including parameters clarifying Mode of Action*'.

6. On 6 May 2015, the Agency sent the draft decision to the addressees of the Contested Decision (the Appellant, SI Group-UK, and Oxiris Chemicals) and invited them, pursuant to Article 50(1), to provide comments.

7. On 12 June 2015, the lead registrant for the Substance (SI Group-UK) provided comments to the Agency on the draft decision on behalf of the addressees of the Contested Decision. The comments included an objection to the request for an EOGRTS on the grounds of insufficient evidence of adverse effects and animal welfare. The registrants proposed instead performing an '*OECD [TG] 422 Combined Repeated Dose Toxicity Study with the Reproductive/Developmental Toxicity Screening Test*'.

8. The draft decision was subsequently revised by the eMSCA (the 'revised draft decision'). However, the requirement to provide information on an EOGRTS remained unchanged.

[1] Commission Regulation (EU) 2015/282 amending Annexes VIII, IX and X to the REACH Regulation as regards the Extended One-Generation Reproductive Toxicity Study (OJ L 50, 21.2.2015, p. 1).

9. On 8 September 2015, the eMSCA notified the revised draft decision to the competent authorities of the other Member States ('MSCAs') and the Agency in accordance with Article 52(1). Five MSCAs and the Agency submitted proposals for amendment in accordance with Articles 51(5) and 52(2).

10. On 14 October 2016, the Agency notified the addressees of the Contested Decision of the proposals for amendment and invited them, pursuant to Articles 52(2) and 51(5), to provide comments on them.

11. According to the Contested Decision, the eMSCA examined the proposals for amendment and amended the revised draft decision (the 'amended draft decision').

12. On 24 October 2016, the Agency referred the amended draft decision to the MSC.

13. By 14 November 2016, the lead registrant for the Substance (SI Group-UK) provided comments on the proposals for amendment on behalf of the addressees of the Contested Decision. According to the Contested Decision, the addressees of the Contested Decision also provided comments on the draft decision but the MSC '*did not take into account [the] comments on the draft decision that were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5)*'.

14. The amended draft decision was discussed at the MSC meeting of 12 to 16 December 2016. On 16 December 2016, the MSC reached unanimous agreement on the amended draft decision, as further modified at the meeting. With regards to the EOGRTS, the minutes of MSC meeting state that '*[the] MSC unanimously agreed to keep the request for EOGRTS in rats, (oral route, with the registered substance), with cohorts 1A, cohorts 2A and 2B (developmental neurotoxicity) and cohort 3 (Developmental immunotoxicity). Inclusion of the request to mate cohort 1B animals to produce the F2 generation allowed for a reduction of the premating period for the parental (P0) generation from 10 weeks to two weeks. In addition MSC unanimously agreed to remove the additional mechanistic parameters from the EOGRTS test*'.

15. On 23 March 2017, the Contested Decision was adopted by the Agency requiring the three addressees of that Decision to update their registration dossiers by 1 July 2019 with information including:

    '*[EOGRTS] (OECD TG 443) in rats (oral route), specified as follows:*

    i. *At least two weeks premating exposure duration for the parental (P0) generation;*

    ii. *Dose level setting shall aim to induce some toxicity at the highest dose level;*

    iii. *Cohort 1A (Reproductive toxicity);*

    iv. *Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;*

    v. *Cohorts 2A and 2B (Developmental neurotoxicity); and*

    vi. *Cohort 3 (Developmental immunotoxicity).'*

Procedure before the Board of Appeal

16. On 19 June 2017, the Appellant filed this appeal.

17. On 22 August 2017, the Agency filed its Defence.

18. On 4 October 2017, SI Group-UK and Oxiris Chemicals, co-registrants of the Substance and addressees of the Contested Decision, were jointly granted leave to intervene in support of the Appellant.

19. On 5 October 2017, the eMSCA was granted leave to intervene in support of the Agency.

20. On 26 October 2017, the Appellant filed its observations on the Defence and replied to questions from the Board of Appeal.

21. On 23 November 2017, SI Group-UK/Oxiris Chemicals and the eMSCA filed their respective statements in intervention.

22. On 11 December 2017, the Agency filed observations on the Appellant's observations on the Defence and replied to questions from the Board of Appeal.

23. On 20 and 21 December 2017, the Appellant and the Agency filed their respective observations on the statements in intervention.

24. On 20 March 2018, a hearing was held at the Appellant's request. At the hearing, the Parties and the Interveners made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

25. The Appellant, supported by SI Group-UK/Oxiris Chemicals, requests the Board of Appeal to:

    - annul Section 1 of Part II and Section 1 of Part III of the Contested Decision regarding '*Concerns on endocrine disruption and reproductive toxicity*', which require the addressees of the Contested Decision to conduct an EOGRTS (OECD TG 443), and
    - order the refund of the appeal fee.

26. The Agency, supported by the eMSCA, requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

Breach of Articles 41(1), 42(2) and 47(1), and the principle of proportionality through the use of the substance evaluation procedure instead of the compliance check procedure

Arguments of the Appellant and SI Group-UK/Oxiris Chemicals

27. The Appellant argues that, pursuant to Columns 1 and 2 of Section 8.7.3. of Annex IX and Section 8.7.3. of Annex X, the EOGRTS requested in the Contested Decision is a requirement for the registration of substances in quantities of 1 000 tonnes or more per year, and in some cases in quantities of 100 tonnes or more per year. Since the Appellant has registered the Substance at the 10 to 100 tonnes per year tonnage band, it is not an information requirement for its own registration.

28. The Appellant, basing itself on the Board of Appeal's decision of 23 September 2015 in Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, argues that the Agency should have conducted a compliance check, under dossier evaluation, of the registrations for the Substance at the 100 to 1 000 tonnes per year tonnage band prior to the substance evaluation of the Substance. If appropriate, the Agency should then have requested the EOGRTS under the compliance check procedure from the registrants at the 100 to 1 000 tonnes per year tonnage band. Substance evaluation should not be used to fill information gaps in registration dossiers. By failing to follow the normal course of action foreseen in the REACH Regulation, the Agency breached Articles 41(1), 42(2) and 47(1) taken together, as well as the principle of proportionality.

29. The Appellant argues that, by requesting the EOGRTS under substance evaluation, the Agency exposed it to considerable costs. It would not have been exposed to those costs if an EOGRTS had been provided in the 100 to 1 000 tonnes per year tonnage band registrations, or if the Agency had requested an EOGRTS from the registrants at the 100 to 1 000 tonnes per year tonnage band following a compliance check.

30. The Appellant, supported by SI Group-UK/Oxiris Chemicals, argues that the Agency therefore breached the principle of proportionality as it did not adequately justify requesting information from all registrants under the substance evaluation procedure that was potentially a registration requirement for some registrants. The Contested Decision puts the Appellant in a less favourable position compared to the situation where a compliance check had been conducted beforehand. The Contested Decision is therefore not the least onerous measure for the Appellant.

31. SI Group-UK/Oxiris Chemicals argue that '*the EOGRTS was not triggered as a requirement*' under Column 1 of Section 8.7.3. of Annex IX. They also argue that the Agency failed to identify a risk to justify requesting information under substance evaluation or to demonstrate how the EOGRTS might lead to improved risk management measures.

Arguments of the Agency and the eMSCA

32. The Agency, supported by the eMSCA, argues that, pursuant to Article 46(1), under substance evaluation it is permitted to request either the standard information required for registration purposes in the Annexes to the REACH Regulation or additional information.

33. The Agency argues that the REACH Regulation does not dictate the order in which dossier evaluation and substance evaluation should be conducted. In the circumstances of the present case, requiring a dossier evaluation before substance evaluation would have delayed the substance evaluation process by several years.

34. The Agency argues that the substance evaluation process was the correct process to follow in the present case as the request for an EOGRTS is concern driven. There is a concern for reproductive toxicity '*that fits to the standard information requirement of*' Section 8.7.3. of Annexes IX and X, and a concern for endocrine disruption. The Contested Decision does not aim to fill a data-gap but rather addresses a concern.

35. The Agency argues that, when the substance evaluation process for the Substance was started, the EOGRTS was not a standard information requirement. An EOGRTS only became a standard information requirement on 13 March 2015 with the entry into force of Commission Regulation (EU) 2015/282.

36. The Agency argues that in the draft decision additional parameters were included in the request for an EOGRTS which went beyond the standard information requirement for registration purposes. However, these additional parameters were removed from the Contested Decision at the MSC.

37. The Agency argues that, under substance evaluation, the evaluation of available information goes beyond evaluating the registration dossiers for a substance. The eMSCA additionally carrying out, for example, a literature search. In the present case, the Agency would not have had the information necessary to justify requesting certain of the parameters for the EOGRTS following a compliance check.

38. The Agency argues that the Appellant's rights were not prejudiced by the request for an EOGRTS under the substance evaluation process because:

    - an EOGRTS can also be a registration requirement, under Annex VIII, for the tonnage band at which the Appellant registered the Substance,
    - the Appellant contributes to the potential risk posed by the Substance and has the obligation to ensure its safe use, and
    - pursuant to Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with the REACH Regulation (OJ L 3, 6.1.2016, p. 41), it is for all registrants of a substance to agree on the arrangements to share costs and data arising from a substance evaluation decision.

39. The Agency argues that there is no breach of the principle of proportionality as the potential risk posed by the Substance for reproductive toxicity and endocrine disruption requires the generation of new data. An EOGRTS will provide that data and, as a result, the requested study is appropriate and necessary. There are also no suitable alternatives to the EOGRTS to clarify the concerns identified.

Findings of the Board of Appeal

40. The Appellant argues, in essence, that before requesting an EOGRTS from the Appellant under substance evaluation the Agency should have carried out a compliance check. If the compliance check identified a data-gap the Agency should have requested an EOGRTS from the registrants registering the Substance at the 100 to 1 000 tonnes per year tonnage band (Annex IX). According to the Appellant, by not following the normal course of action foreseen in the REACH Regulation, the Agency breached Articles 41(1), 42(2) and 47(1) taken together, as well as the principle of proportionality.

41. In examining the Appellant's arguments the Board of Appeal will consider whether:

- the EOGRTS in the form requested in the Contested Decision is a registration requirement pursuant to the Annexes to the REACH Regulation, and
- the Agency should have requested the EOGRTS under a compliance check rather than following a substance evaluation.

EOGRTS as a registration requirement

42. Pursuant to Article 10(a)(vi) and (vii), a registration dossier must include study summaries or, if required under Annex I, robust study summaries, of the information derived from the application of Annexes VII to XI.

43. The information that must be provided for registration purposes includes the '*standard information*' set out, depending on the tonnage band at which the substance is registered, in Annexes VII to X (the 'testing Annexes'). Annex XI and Column 2 of Annexes VII to X detail how the information required by the testing Annexes can be adapted for registration purposes.

44. In the present case, the Appellant registered the Substance at the 10 to 100 tonnes per year tonnage band. Pursuant to Article 12(1)(c), subject to the application of any adaptations, its registration dossier must, amongst other things, include the information specified in Annexes VII and VIII.

45. SI Group-UK and Oxiris Chemicals registered the Substance at the 100 to 1 000 tonnes per year tonnage band. Pursuant to Article 12(1)(d), subject to the application of any adaptations, their registration dossiers must include, amongst other things, '*the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX*'.

46. A reference to the requirement to provide information on an EOGRTS appears for the first time in the last paragraph of Column 2 of Section 8.7.1. of Annex VIII:

'*In cases where there are serious concerns about the potential for adverse effects on fertility or development, either an [EOGRTS] (Annex IX, section 8.7.3) or a pre-natal developmental toxicity study (Annex IX, section 8.7.2) may, as appropriate, be proposed by the registrant instead of the screening study [required in Column 1].*'

47. It is therefore possible that registrants at the 10 to 100 tonnes per year tonnage band, such as the Appellant, need to provide information on an EOGRTS for registration purposes. The Agency can check the requirement to provide an EOGRTS at the Annex VIII level under the compliance check procedure pursuant to Article 41(1). A decision requiring an EOGRTS from a registrant at the 10 to 100 tonnes per year tonnage band, if the available information shows '*serious concerns about the potential for adverse*

effects on fertility or development', may therefore be a consequence of a compliance check.

48. Pursuant to Column 1 of Section 8.7.3. of Annex IX, the following is a registration requirement:

'*[EOGRTS] (B.56 of the Commission Regulation on test methods as specified in Article 13(3) or OECD [TG] 443), basic test design (cohorts 1A and 1B without extension to include a F2 generation), one species, most appropriate route of administration, having regard to the likely route of human exposure, if the available repeated dose toxicity studies (e.g. 28-day or 90- day studies, OECD [TG] 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity*'.

49. Pursuant to Column 2 of Section 8.7.3. of Annex IX, an EOGRTS for registration purposes can be extended to include additional parameters:

'*An [EOGRTS] with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41, if:*

(a) the substance has uses leading to significant exposure of consumers or professionals, taking into account, inter alia, consumer exposure from articles, and

(b) any of the following conditions are met:

- *the substance displays genotoxic effects in somatic cell mutagenicity tests in vivo which could lead to classifying it as Mutagen Category 2, or*
- *there are indications that the internal dose for the substance and/or any of its metabolites will reach a steady state in the test animals only after an extended exposure, or*
- *there are indications of one or more relevant modes of action related to endocrine disruption from available in vivo studies or non-animal approaches.*

An [EOGRTS] including cohorts 2A/2B (developmental neurotoxicity) and/ or cohort 3 (developmental immunotoxicity) shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41, in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following:

- *existing information on the substance itself derived from relevant available in vivo or non-animal approaches (e.g. abnormalities of the CNS, evidence of adverse effects on the nervous or immune system in studies on adult animals or animals exposed prenatally), or*
- *specific mechanisms/modes of action of the substance with an association to (developmental) neurotoxicity and/or (developmental) immunotoxicity (e.g. cholinesterase inhibition or relevant changes in thyroidal hormone levels associated to adverse effects), or*
- *existing information on effects caused by substances structurally analogous to the substance being studied, suggesting such effects or mechanisms/modes of action.*

Other studies on developmental neurotoxicity and/or developmental immunotoxicity instead of cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) of the [EOGRTS] may be proposed by the registrant in order to clarify the concern on developmental toxicity.

Two-generation reproductive toxicity studies (B.35, OECD TG 416) that were initiated before 13 March 2015 shall be considered appropriate to address this standard information requirement.

The study shall be performed on one species. The need to perform a study at this tonnage level or the next on a second strain or a second species may be considered and a decision should be based on the outcome of the first test and all other relevant available data.'

50. Registrants at the 100 to 1 000 tonnes per year tonnage band, such as SI Group-UK and Oxiris Chemicals, therefore may need to provide information on an EOGRTS for registration purposes, subject to the application of any adaptations. The Agency can check the requirement to provide an EOGRTS at the Annex IX level under the compliance check procedure pursuant to Article 41(1).

51. Furthermore, the registration requirement following the application of Columns 1 and 2 of Section 8.7.3. of Annex IX can be the same as the EOGRTS set out in the Contested Decision (see paragraph 15 above). The EOGRTS in the form set out in the Contested Decision may, in certain circumstances, also be a registration requirement for registrants, such as the Appellant, at the 10 to 100 tonnes per year tonnage band (Annex VIII) (see paragraphs 46 and 47 above). The Agency confirmed during these proceedings that this was also its position in this regard. The EOGRTS requested in the Contested Decision could therefore potentially have been requested from the Appellant, SI Group-UK and Oxiris Chemicals under the compliance check procedure.

52. The EOGRTS became a registration requirement on 13 March 2015 with the entry into force of Commission Regulation (EU) 2015/282 (see paragraph 4 above). An EOGRTS in the form set out in the Contested Decision was therefore a possible registration requirement prior to the date on which the draft decision was sent to the addressees for their comments (see paragraph 6 above).

53. In view of the above, the EOGRTS in the form set out in the Contested Decision may be a registration requirement for all of the addressees of the Contested Decision (i.e. pursuant to Annexes VIII and IX). Therefore, an EOGRTS could have been required following a compliance check from all, some, or none of the registrants of the Substance. Consequently, the Board of Appeal will examine whether the Agency committed an error in the present case in requesting an EOGRTS following substance evaluation instead of a compliance check.

The Agency's choice of procedure for requesting the EOGRTS

54. Where the information required to satisfy Section 8.7.3. of Annex IX or, in certain cases, Column 2 of Section 8.7.1. of Annex VIII, or alternatively a testing proposal for an EOGRTS, has not been included in a registration dossier, the Agency may require an EOGRTS following a compliance check pursuant to Article 41 (see paragraphs 47 and 50 above). In the present case, the Agency requested the information under substance evaluation pursuant to Article 46.

55. Whilst the REACH Regulation contains no explicit requirement that a compliance check should precede substance evaluation, 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 (see Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others,* Decision of the Board of Appeal of 23 September 2015, paragraphs 77 to 80).

56. Although a compliance check should normally precede substance evaluation, the information requirements set out in Annexes VII to X may, in certain circumstances, also be requested under substance evaluation (see, for example, Case A-023-2015, *Akzo Nobel Chemicals and Others*, Decision of the Board of Appeal of 13 December 2017, paragraph 123 and Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others,* Decision of the Board of Appeal of 23 September 2015, paragraphs 77 to 90).

57. The Agency has a margin of discretion regarding the choice of procedure that it follows to request information that is a registration requirement. However, when exercising its discretion, the Agency is required to take into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (see, by analogy, judgment of 7 March 2013, *Rütgers Germany and Others* v *ECHA*, T-96/10, EU:T:2013:109, paragraph 100, and Case A-001-2014, *CINIC Chemicals Europe*, Decision of the Board of Appeal of 10 June 2015, paragraph 74).

58. When requesting standard information for registration purposes under the substance evaluation procedure rather than the compliance check procedure, the Agency must be able to demonstrate that the substance concerned presents a potential risk to human health or the environment. In addition, the rights of all registrants of the substance concerned must not be prejudiced by the Agency's choice of procedure (see Case A-023-2015, *Akzo Nobel Chemicals and Others*, Decision of the Board of Appeal of 13 December 2017, paragraph 123).

59. As confirmed by the Appellant at the hearing, the issue of a potential risk is not a subject of the present appeal. The Board of Appeal will therefore examine whether the rights of any of the registrants of the Substance were prejudiced by the Agency's decision to require the contested information requirement following the substance evaluation procedure, rather than the compliance check procedure.

60. Pursuant to Article 53(2), '*[if] a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally*'. The requirement for all addressees of the Contested Decision to share the costs of generating the information requested is also set out in Section V of the Contested Decision. Under the Contested Decision, the Appellant, SI Group-UK and Oxiris Chemicals are all therefore required to pay a share of the costs incurred through the generation of the information required in the Contested Decision.

61. Pursuant to Article 4(1) of Commission Regulation (EU) 2016/9, '*…any registrant of a substance shall only be required to share the costs of information that such registrant is obliged to submit to the Agency to satisfy his registration requirements under [the REACH Regulation]*'. In the present case, if the Agency had requested an EOGRTS under the compliance check procedure pursuant to Section 8.7.3. of Annex IX from those registrants registering the Substance at 100 to 1 000 tonnes per year only, the Appellant would not have been required to pay a share of the costs related to the performance of that study. This is because it registered the Substance at the 10 to 100 tonnes per year tonnage band (Annex VIII).

62. In the circumstances described in paragraphs 60 and 61 above, the Appellant's rights would therefore have been prejudiced by the Agency's decision to request the EOGRTS under substance evaluation rather than following a compliance check. Under the Contested Decision the Appellant could be required to pay a share of the costs of the EOGRTS whilst it may not need that information for registration purposes. If an EOGRTS had been provided by the higher tonnage registrants as standard information an EOGRTS would not be needed under substance evaluation and the Appellant would not be required to contribute to the cost of performing an EOGRTS following a substance evaluation decision.

63. 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 required to meet such costs if the standard information had been provided through a registration by a higher volume registrant (Case A-005-2014, *Akzo Nobel*

Industrial Chemicals and Others, Decision of the Board of Appeal of 23 September 2015, paragraph 86).

64. However, as set out in paragraphs 46 and 47 above, registrants at the Annex VIII level, such as the Appellant, may be required to provide information on an EOGRTS pursuant to Column 2 of Section 8.7.1. of Annex VIII. Registrants may propose performing an EOGRTS at the Annex VIII level, instead of a screening study (OECD TG 421 or 422), if there are '*serious concerns about the potential for adverse effects on fertility or development*'.

65. In the present case, the Contested Decision does not contain any assessment of whether there were such '*serious concerns*'. In addition, there has been no compliance check of the Appellant's registration dossier at any time regarding this information requirement. It is therefore not known whether the EOGRTS should be provided under Annex VIII and, if so, which of the possible parameters for an EOGRTS would be required.

66. Without knowing which of the registrants of the Substance are required to provide information on an EOGRTS for registration purposes to address the reproductive toxicity endpoint, and which detailed form the EOGRTS may take, it is not known which of those registrants would be required to pay a share of the costs of the study in order to meet their registration obligations.

67. If the Agency had addressed the substance evaluation decision only to the registrants registering the Substance at 100 to 1 000 tonnes per year (Annex IX), it is possible that their rights would have also been prejudiced. This is because there has been no evaluation of whether the available information shows '*serious concerns about the potential for adverse effects on fertility or development*' within the meaning of Column 2 of Section 8.7.1. of Annex VIII and therefore whether the Appellant should also be required to provide information on an EOGRTS for registration purposes.

68. In light of the above, it is clear that the rights of the Appellant may have been prejudiced by the Agency's failure to assess, at any time or through any procedure, whether there were '*serious concerns about the potential for adverse effects on fertility or development*' and therefore whether the EOGRTS requested in the Contested Decision was an information requirement for Appellant, or SI Group-UK and Oxiris Chemicals, or all three of those registrants of the Substance.

69. In conclusion, as the Agency did not carry out an assessment of which registrants would be required to provide the EOGRTS for registration purposes, at any time or through any procedure, it is not known which of the registrants of the Substance should be required to pay a share of the costs relating to the performance of that test. The Agency did not therefore take into consideration all the relevant factors and circumstances of this particular case. The requirement to perform an EOGRTS must therefore be annulled and the case remitted to the Agency for further action.

70. As the requirement to provide information on an EOGRTS has been annulled, it is not necessary to examine the Appellant's other pleas.

Refund of the appeal fee

71. 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 the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.

72. As the appeal has been decided in favour of the Appellant, the appeal fee shall be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Agency's Decision of 23 March 2017 on the substance evaluation of 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol in so far as it requests information on an EOGRTS (OECD TG 443) in rats (oral route).**
2. **Remits the case to the competent body of the Agency for further action.**
3. **Decides that the appeal fee must be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Marc GOODACRE
Acting as Registrar of the Board of Appeal