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) – Soil simulation testing)

Case number	A-008-2017
Language of the case	English
Appellants	SI Group-UK Ltd, United Kingdom, and Oxiris Chemicals S.A, Spain
Representatives	Claudio Mereu and Maud Grunchard, Fieldfisher (Belgium) LLP, Belgium
Interveners	(I) Infineum UK Ltd, United Kingdom Represented by: Jean-Philippe Montfort and Thomas Delille Mayer Brown Europe-Brussels 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 Appellants 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 100 to 1 000 tonnes per year tonnage band. The Intervener, Infineum UK, registered the Substance at the 10 to 100 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*'; and

   'Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23./OECD [TG] 307)'.

6. On 6 May 2015, the Agency sent the draft decision to the addressees of the Contested Decision (the Appellants and Infineum UK) 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*'. In relation to the soil simulation testing requested, the Appellants stated in the comments, amongst other things, that '*the registrant agrees to carry out an OECD 307 study. It is requested*

[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).

the percentage level of identification of transformation products ("reasonable attempts should be made to quantify these down to 0.1 %") be revised as it is unlikely that this is achievable. The OECD 307 guideline and general laboratory practice is for the measurement of transformation products to be at the 10 % level. The registrant proposes to investigate the relevance of abiotic processes (e.g. photolysis and hydrolysis) to degradation in parallel'.

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

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 published minutes of the 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. With regards to the soil simulation testing, the published minutes of the MSC meeting state that: '*…Regarding the persistency and toxicity assessment [the] MSC unanimously agreed to request only the soil simulation test at this stage using radioactively ^{14}C ring-labelled test substance and conducting the kinetic part of the test at 12 °C and identification of potential metabolites at 20 °C. Depending on the outcome of this test, the eMSCA will consider the need for further testing in sediment in the follow-up stage. MSC also unanimously agreed not to test for terrestrial toxicity until it is determined that the substance is P or vP*'.

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

'*Concerns on endocrine disruption and reproductive toxicity*

1. [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).*

Concern on persistency, bioaccumulation and toxicity (PBT)

2. *Soil simulation testing (test method: Aerobic and anaerobic transformation in soil, EU C.23/OECD 307) […] using radioactivity ^{14}C ring-labelled test substance. The kinetic part of the test shall be conducted at 12°C. For the identification of potential metabolites 20°C shall be used.'*

Procedure before the Board of Appeal

17. On 23 June 2017, the Appellants filed this appeal.

18. On 28 August 2017, the Agency filed its Defence.

19. On 10 October 2017, the eMSCA was granted leave to intervene in support of the Agency.

20. On 11 October 2017, Infineum UK, a co-registrant of the Substance and an addressee of the Contested Decision, was granted leave to intervene in support of the Appellants.

21. On 10 November 2017, the Appellants filed their observations on the Defence and replied to questions from the Board of Appeal.

22. On 13 November 2017, Infineum UK informed the Board of Appeal that it did not wish to submit a statement in intervention.

23. On 27 November 2017, the eMSCA filed its statement in intervention.

24. On 20 December 2017, the Agency filed observations on the Appellants' observations on the Defence and replied to questions from the Board of Appeal.

25. On 21 December 2017, the Agency and the Appellants filed their respective observations on the eMSCA's statement in intervention.

26. On 21 March 2018, a hearing was held at the Appellants' request. At the hearing, the Parties and the Intervener made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

27. The Appellants, supported by Infineum UK, request the Board of Appeal to annul the Contested Decision '*insofar as it requires the submission of: (i) the EOGRTS and (ii) the soil simulation testing*'.

28. In the alternative, the Appellants request the annulment of the Contested Decision '*insofar as it requires the submission of: (i) the EOGRTS, with additional parameters ([extension] to F2, additional cohorts and no DRF [dose-range-finding]) and (ii) the soil simulation testing to be conducted with strong extraction techniques, detection of degraded metabolites at 0.1 % and additional testing at 20 °C*'.

29. The Appellants also request the Board of Appeal to order the Agency to pay the costs of the proceedings.

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

Reasons

31. In Section 1 below the Board of Appeal will examine the Appellants' pleas related to the requirement to perform an EOGRTS. In Section 2 below the Board of Appeal will examine the Appellants' pleas related to the requirement to perform soil simulation testing.

1. Pleas related to the requirement to perform an EOGRTS

32. In relation to the requirement to perform an EOGRTS the Appellants raise the following pleas:

- Breach of Article 46,
- Breach of the duty to state reasons,
- Error of assessment on the grounds that the EOGRTS is:
  - Scientifically unjustified, and
  - Inappropriate to address the concern identified by the Agency,
- Breach of the principle of proportionality and animal welfare requirements, and
- Breach of procedural requirements by requesting the EOGRTS under substance evaluation rather than under dossier evaluation.

33. The Board of Appeal will first examine the Appellants' plea regarding the choice of procedure for requesting the EOGRTS.

1.1 Breach of procedural requirements by requesting the EOGRTS under substance evaluation rather than under dossier evaluation

Arguments of the Appellants

34. The Appellants, basing themselves on the Board of Appeal's decision of 23 September 2015 in Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, argue that the Agency should have first examined the registration dossiers for the Substance in a compliance check under Article 41 before undertaking a substance evaluation.

Arguments of the Agency and the eMSCA

35. The Agency, supported by the eMSCA, argues that at the 100 to 1 000 tonnes per year tonnage band there is no requirement for an EOGRTS unless specific criteria are met. The Agency argues that the Appellants '*neither provided their considerations in the registration dossier as to whether or how to adapt the information requirement under Annex IX/X, 8.7.3, nor did they submit their considerations as to why the triggers for the EOGRTS would not be met at this tonnage level*'.

36. The Agency argues that substance evaluation is the right process to be followed in this case because '*there are concern-driven indications that require to request specific modifications of the study design*'.

37. The Agency argues that a registrant's participatory rights in the substance evaluation and dossier evaluation procedures are comparable. As a result, the Appellants failed to establish a procedural flaw or how the use of the substance evaluation process prejudiced their rights.

Findings of the Board of Appeal

38. The Appellants argue, in essence, that the Agency should have first examined the registration dossiers for the Substance in a compliance check under Article 41 before undertaking a substance evaluation. If the compliance check identified a data-gap the Agency should have requested an EOGRTS under that procedure. According to the Appellants, by not following this normal course of action, the Agency breached the procedural requirements of the REACH Regulation.

39. In examining the Appellants' 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 following a compliance check rather than following a substance evaluation.

1.1.1. EOGRTS as a registration requirement

40. 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.

41. 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.

42. In the present case Infineum UK 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.

43. The Appellants 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*'.

44. 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].*'

45. It is therefore possible that registrants at the 10 to 100 tonnes per year tonnage band, such as Infineum UK, 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.

46. 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'.

47. 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.'

48. Registrants at the 100 to 1 000 tonnes per year tonnage band, such as the Appellants, 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).

49. 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 16 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 Infineum UK, at the 10 to 100 tonnes per year tonnage band (Annex VIII) (see paragraphs 44 and 45 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 Appellants and Infineum UK under the compliance check procedure.

50. 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).

51. 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 a substance evaluation instead of a compliance check.

1.1.2. The Agency's choice of procedure for requesting the EOGRTS

52. 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 45 and 48 above). In the present case, the Agency requested the information under substance evaluation pursuant to Article 46.

53. 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).

54. 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).

55. 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).

56. 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).

57. The Board of Appeal will first 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.

58. 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 Appellants and Infineum UK are all therefore required to pay a share of the costs incurred through the generation of the information required in the Contested Decision.

59. Pursuant to Article 4(1) of 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) '*…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, Infineum UK 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).

60. In the circumstances described in paragraphs 58 and 59 above, Infineum UK'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 Infineum UK 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 Infineum UK would not be required to contribute to the cost of performing an EOGRTS following a substance evaluation decision.

61. 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).

62. However, as set out in paragraphs 44 and 45 above, registrants at the Annex VIII level, such as Infineum UK, 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*'.

63. 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 Infineum UK'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.

64. 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.

65. If the Agency had addressed the substance evaluation decision only to the Appellants, as registrants of the Substance at 100 to 1 000 tonnes per year (Annex IX level), 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 Infineum UK should also be required to provide information on an EOGRTS for registration purposes.

66. In light of the above, it is clear that the rights of Infineum UK and the Appellants 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 Infineum UK or the Appellants or both.

67. 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.

68. As the requirement to provide information on an EOGRTS has been annulled, it is not necessary to examine the Appellants' other pleas in this regard.

2 Pleas concerning the requirement to provide information on soil simulation testing

69. At the oral hearing, the Appellants clarified that they agree to conduct soil simulation testing but contest certain of the parameters specified in the Contested Decision for performing that test. The Appellants made a similar statement during the decision-making process. According to the Contested Decision, '*[i]n your comments you agreed to conduct the requested OECD [TG] 307 study. However, you stated that the requested % level of identification of transformation products is unlikely to be achieved*'.

70. In the Notice of Appeal the Appellants also state that '*…should the Board of Appeal not annul the Contested Decision for the reasons given under [Section A of the Notice of Appeal], the Appellants accept that they should carry out the soil simulation testing requested by [the Agency] in the Contested Decision, but submit that the study designs cannot be accepted. Those designs are imposed as an error of assessment*'.

71. Section A of the Notice of Appeal is entitled '*Infringement of Article 46 of REACH/Lack of Statement of Reasons*'. With regards to the infringement of Article 46, the Appellants argue that the Agency has failed to establish a concern justifying the request for soil simulation testing. However, the Appellants' arguments in that Section relate to potential endocrine disrupting properties and reproductive toxicity which are the concerns used by the Agency to justify the request for the EOGRTS. In relation to the

soil simulation testing, the Appellants limit themselves to stating that '*this is also relevant for the request for soil simulation testing, which is also based on alleged concerns regarding properties of the substance and which is not based on sufficient justification in particular for the testing parameters which go further than the standard information requirements of REACH…*'.

72. It is therefore clear on the basis of the Notice of Appeal and the statements presented at the oral hearing that the Appellants contest the additional parameters of the soil simulation testing and not the requirement to perform the test itself. The Appellants additionally claim that had the Agency requested the soil simulation testing without the additional parameters, it should have used the compliance check procedure rather than the substance evaluation procedure.

73. The Board of Appeal will therefore first examine, in Section 2.1. below, the Appellants' pleas regarding an error of assessment and proportionality in relation to three of the parameters for performing the test set out in the Contested Decision, that is the requirement to use strong extraction techniques, quantification of transformation products down to 0.1 %, and testing at 12 °C and 20 °C. Second, in Section 2.2. below, the Board of Appeal will examine the Appellants' plea regarding the breach of the duty to state reasons. Finally, in Section 2.3. below, the Board of Appeal will examine whether the Agency committed a breach of the procedural requirements of the REACH Regulation by requesting the soil simulation testing under the substance evaluation procedure rather than the compliance check procedure.

2.1. Error of assessment and proportionality regarding the parameters of the soil simulation testing

74. The Appellants claim an error of assessment and a breach of the principle of proportionality with regards to the following three requirements of the soil simulation testing:

- The requirement to use '*strong extractions, such as soxhlet-extraction with apolar solvents*',
- The requirement that '*transformation products formed at levels of 1 % or more of the test substance shall be [assessed], with reasonable attempts made to quantify these down to 0.1 %*', and
- The requirement for testing to be conducted at 12 °C and 20 °C.

75. With regard to the alleged error of assessment it is necessary to examine whether the Agency has examined carefully and impartially all the relevant facts of the individual case which support the conclusions reached (see, by analogy, judgment of 19 January 2012, *Xeda International and Pace International* v *Commission*, T-71/10, EU:T:2012:18, paragraph 71; Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 42).

76. In order to respect the principle of proportionality, measures adopted by the European Union institutions must 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 (judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124; Case A-005-2011, *Honeywell Belgium*, Decision of the Board of Appeal of 29 April 2013, paragraphs 115 to 117).

2.1.1. The requirement to use strong extraction techniques

Arguments of the Appellants

77. The Appellants argue that strong extraction techniques should not be used to extract non-irreversibly bound fractions as the Substance is extractable and stable. According to the Appellants, the '*use of strong extraction techniques would lead to over-estimation of the bioavailable fraction and false positive outcome*'. Strong extraction techniques can also undermine the integrity of samples and should be used only as a last resort.

78. The Appellants argue that the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Technical Report Number 117 on '*Understanding the relationship between extraction technique and bioavailability'* (27 May 2013, the 'ECETOC Report') recommends using '*a phased approach where other extraction methods should be used first and harsh extraction methods'* only as a last resort.

79. The Appellants argue that the Agency's Guidance on Information Requirements and Chemical Safety Assessment (Version 3.0, February 2016, Chapter R.7b), which addresses extraction techniques, says that strong extraction techniques are rarely employed in soil simulation testing.

80. The Appellants also claim that this requirement is disproportionate.

Arguments of the Agency and the eMSCA

81. The Agency, supported by the eMSCA, argues that the extraction procedures/solvents mentioned in the Contested Decision are not mandatory.

82. The Agency argues that '*in the OECD TG 307 test, the [non extractable residue ('NER')] formation and how much of it is non-irreversibly bound is case-specific and depends on the substance properties, the specific test conditions and the experimental setup applied*'. As a result, no specific extraction techniques/solvents were required, only examples are given.

83. The Agency argues that the intrinsic properties of the Substance (low water solubility, high apolarity, high log K_{oc}) indicate that soil is a relevant compartment for testing and that the Substance has a high tendency to bind to soil. Therefore strong extraction procedures/solvents are needed.

84. The Agency argues that the ECETOC Report and the ECHA Guidance on Information Requirements and Chemical Safety Assessment do not state that strong extraction techniques cannot be used.

85. The Agency argues that the Appellants are requested to demonstrate that the fraction of the Substance which is not extracted from the soil by the method chosen is irreversibly bound to the soil (i.e. non-extractable) and therefore will not pose a risk to the environment. The Agency argues that if *'this is not demonstrated, a worst-case approach applies and any residue will be considered as non-degraded, which will impact the calculated half-life to be compared against the [persistence] criterion*'.

Findings of the Board of Appeal

86. The Contested Decision specifies that:

'*It is possible or even likely that the substance may form non-extractable residues (NER) in soil. You are therefore requested to justify scientifically that the extraction procedure/solvent chosen is appropriate to completely extract the non-irreversibly bound fraction of the substance/its metabolites from the soil matrix. Strong extractions, <u>such as</u> soxhlet-extraction with apolar solvents, should be used in order to conclude that the remaining part should be considered as irreversibly bound fraction*' (emphasis added).

87. According to the Contested Decision, the Substance '*is not readily biodegradable*'. The aim of the requested test is to examine whether the Substance is persistent or very persistent.

88. As stated in the Contested Decision, and not contested by the Appellants, '*based on the intrinsic properties of the [Substance], (e.g. low water solubility, high apolarity, high log K_{oc}), soil is a compartment of concern*'. These properties indicate that the Substance may have a high tendency to be bound to soil particles.

89. As the Substance may form NERs in soil, the Contested Decision requests the Appellants to '*justify scientifically that the extraction procedure/solvent chosen is appropriate to completely extract the non-irreversibly bound fraction of the substance/its metabolites from the soil matrix'* (emphasis added).

90. During the present proceedings, the Agency stated that the Contested Decision does not prescribe the precise extraction procedure/solvent to be employed during the testing, only that '*strong extractions…should be used'*. The choice of extraction procedure/solvent must be sufficient to ensure the complete extraction of the non-irreversibly bound fraction of the Substance from the soil matrix. The choice of extraction procedure/solvent must be justified by the Appellants accordingly.

91. It is clear from the use of the words '*such as*' and the requirement to justify the method used that the Contested Decision does not prescribe which extraction procedure/solvent should be employed. The Contested Decision only makes suggestions as to which extraction procedures/solvents may be appropriate. This offers guidance to the Appellants as to the appropriate technique to achieve the objective of the Contested Decision. The Contested Decision is however clear that whichever procedure/solvent is employed, the Appellants must demonstrate that it is sufficient to extract the non-irreversibly bound fraction from the soil matrix and that the remaining part is the irreversibly bound fraction.

92. According to the Appellants, the ECETOC Report recommends a phased approach to extraction with strong extraction only being used as a last resort. The Contested Decision, however, does not prevent the Appellants from employing a phased approach to achieve the aim of ensuring the complete extraction of the non-irreversibly bound fraction of the Substance from the soil matrix. If the Appellants can show that by use of various techniques all the non-irreversibly bound fraction of the Substance can be extracted from the soil matrix then there is no need to use strong extraction techniques.

93. Similarly, the Agency's Guidance on Information Requirements and Chemical Safety Assessment does not exclude the possibility of strong extraction procedures being employed. Rather it states that '*the use of strong acids, bases or refluxing could undoubtedly extract the sample more thoroughly but could alter both the substances of interest and the soil/sediment matrices. Such severe extraction techniques are therefore rarely employed in e.g. routine soil or sediment/water testing. The extraction methods and efficiencies as well as analytical methods and detection limits should always be reported*'. Substances which have a high tendency to bind to soil particles are examples of substances which may require the use of such procedures. The Contested Decision and the Guidance are therefore not inconsistent.

94. If the Appellants consider that strong extraction procedures/solvents are not necessary, or feasible, they would need to justify the reasons for this in their registration update. That justification will then be assessed in the follow-up to the Contested Decision pursuant to Article 46(3). If it is considered that the extraction procedure/solvents used are insufficient to completely extract the non-irreversibly bound fraction of the Substance/its metabolites from the soil matrix, this would have to be justified accordingly in any follow-up decision.

95. The expert statement submitted with the Notice of Appeal also suggests that strong extraction techniques may be necessary. According to the expert statement:

'*In house knowledge indicates that the extraction of alkyl phenols from soil or sediment can be challenging due to their strong adsorption tendency. Therefore, harsh extraction conditions (e.g. soxhlet or accelerated solvent extraction (ASE)) are probably already necessary in the initial phase of a soil simulation study to recover the test item as much as possible from soil. This is in accordance to the thoughts of [the Agency] who assume formation of NERs for the test item. Soxhlet extraction as well as ASE are acknowledged methods for the extraction of NER type 1 residues*' (emphasis added).

96. In light of the above, the Agency did not commit an error of assessment regarding the extraction techniques to be employed in the soil simulation testing. For the same reasons, the Agency did not breach the principle of proportionality. The Appellants' arguments must therefore be rejected.

2.1.2. The requirement that transformation products formed at levels of 1 % or more of the test substance shall be assessed with reasonable attempts made to quantify these down to 0.1 %

Arguments of the Appellants

97. The Appellants argue that the lowering of the limit for identifying transformation and/or degradation products from 10 % to 0.1 % '*is neither plausible nor transparent*'. The Agency misapplied its Guidance on Information Requirements and Chemical Safety Assessment '*since the 0.1 % requirement [applies] to constituents, impurities and additives, but does not refer to transformation and/or degradation products*'. On the contrary, the recommended limit for identification of metabolites is 10 %. The Agency's Guidance documents make no reference to a limit of 0.1 % for identifying transformation and/or degradation products.

98. The Appellants argue that '*quantification of transformation products down to 0.1 % is only possible with radio HPLC [high-performance liquid chromatography] if an additional higher concentration is tested*'. However, '*the use of higher concentrations is not recommended because these concentrations do not reflect a relevant (and low) environmental concentration*'.

99. The Appellants argue that quantification of transformation and/or degradation products down to 0.1 % can possibly be achieved using LC-MS systems with a high resolution mass spectrometer (LC-HRMS). However, these are non-standard methods for OECD TG 307.

100. The Appellants also claim that this requirement is disproportionate.

Arguments of the Agency and the eMSCA

101. The Agency, supported by the eMSCA, argues that the specifications regarding the quantification of transformation and/or degradation products are not mandatory. The Contested Decision allows for flexibility in the actual method(s) used to identify and quantify the transformation and/or degradation products formed during the performance of an OECD TG 307 study.

102. The Agency argues that '*the simulation test guidelines [stipulate] that values lower than 10 % may be warranted depending on the specific cases*'. In the present case it is warranted because there are several potentially persistent transformation and/or degradation products of the Substance and the estimated half-life of the Substance in soil is high. In addition, persistent transformation products might form slowly and therefore might be present in low concentrations and only at the end of the study. In the environment however the continuous release of the Substance may lead to increasing concentrations of these slowly formed persistent transformation products over time.

103. The Agency argues that under Article 46 non-standard methods of testing may be requested.

Findings of the Board of Appeal

104. The Contested Decision specifies that:

'*Transformation products formed at levels of 1 % or more of the test substance shall be [assessed], with reasonable attempts made to quantify these down to 0.1 %.*'

105. Annex XIII, on the criteria for the identification of PBT and vPvB substances, provides that:

'*The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.*

The identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.'

106. During the present proceedings the Parties used the terms '*degradation products*', '*transformation products*', and '*metabolites*'. Although these may have different meanings depending on the context in which they are used, the Board of Appeal will use the term '*transformation and/or degradation products*' (as per Annex XIII) to cover all these terms for the purposes of this appeal.

107. The Board of Appeal has previously held that under substance evaluation it may be appropriate to request information using modified test methods because this helps ensure that information generated pursuant to a substance evaluation decision meets real information needs (see Case A-009-2014, *Albemarle Europe and Others*, Decision of the Board of Appeal of 12 July 2016, paragraphs 193 to 194).

108. As specifically confirmed by the Agency in these proceedings, the request for the Appellants to quantify transformation and/or degradation products between 1 % and 0.1 % is not mandatory. As stated in the Contested Decision, attempts should be made, as far as technically possible, to quantify these down to 0.1 %. A justification shall be provided in the registration dossier update where this is not possible. The meaning of '*technically feasible*' is also explained in the Contested Decision as follows: '*…it has been demonstrated within allocation of reasonable efforts to develop suitable analytical methods and other test procedures to accomplish testing in soil so that reliable results can be generated*'.

109. With regard to a limits of detection down to 0.1 %, the Agency acknowledged that the sensitive analytical methods implied by such a limit of detection are not routinely used and are not standard for OECD TG 307. However, the Appellants themselves acknowledge that a limit of detection down to 0.1 % may be achievable, although this is challenging. In this regard, the Appellants consider that quantification down to 0.1 % could possibly be achieved using LC-MS systems with a high resolution mass spectrometer (see paragraph 99 above).

110. If the Appellants are unable to achieve quantification of the transformation and/or degradation products down to 0.1 %, they should provide a justification to that effect. That justification will then be assessed in the follow-up to the Contested Decision pursuant to Article 46(3). If it is considered that the Appellants had not made reasonable attempts to quantify transformation and/or degradation products down to 0.1 %, this conclusion would have to be justified in any follow-up decision.

111. The Appellants appear to have been aware of the non-mandatory nature of this requirement, and what is required of them in this respect, prior to the adoption of the Contested Decision. For example, in their comments of 14 November 2016 on the proposals for amendment the Appellants stated that *'[a]ny study design for the requested OECD [TG] 307 study will make every effort to achieve a level of 0.1 % as a minimum level of quantification. The registrants are still of the belief that such a low*

level is unlikely to be achieved, however any deviation from this level will be reasonably technically justified, as requested'.

112. The assessment of '*transformation products…down to 0.1 %*' is conditional on technical feasibility and the Appellants making '*reasonable attempts*' to quantify transformation and/or degradation products of the Substance. The Board of Appeal finds therefore that the Agency, in the Contested Decision, did not commit an error of assessment or, for the same reasons, breach the principle of proportionality regarding the quantification of transformation and/or degradation products. The Appellants' arguments must therefore be rejected.

2.1.3. Requirement for testing to be conducted at 12 °C and 20 °C

Arguments of the Appellants

113. The Appellants argue that '*there is no need from a technical point of view to run in parallel a second study at 20 °C'.*

114. The Appellants argue that although the Agency's '*guidance document states that the metabolite part may be conducted at 20 °C*', it is not a requirement.

115. The Appellants argue that there is a concern that '*the pattern of metabolite occurrence is not identical at 20 °C and 12 °C. Even small differences can complicate the study, especially if metabolites [at] ≤ 1 % are assessed*'.

116. The Appellants argue that '*due to the use of sensitive LC-HRMS for metabolite identification it is not necessary to accelerate the formation of degradation products to make their identification and characterisation easier. Therefore … both parts of the study should be run at the same temperature (either 12 or 20 °C) in order to ensure that the same metabolites are generated and in the same concentrations*'.

117. The Appellants also claim that this requirement is disproportionate.

Arguments of the Agency and the eMSCA

118. The Agency, supported by the eMSCA, argues that '*transformation products may form slowly and consequently only be present at low concentrations during the requested degradation study. At 20 °C the formation of potential transformation products is faster and therefore higher concentrations can be reached in a given time compared to 12 °C*'.

119. The Agency argues that *'potentially persistent transformation products need to be considered for [persistence] assessment. Therefore, in light of the expected slow formation [of transformation products] it is […] justified to run the metabolite identification part at 20 °C*'.

Findings of the Board of Appeal

120. The Contested Decision specifies that:

'*The kinetic part of the study shall be performed under aerobic conditions at a constant temperature of 12 °C, since this is a representative temperature for EU soils. Relevant environmental conditions include 12 °C [.] The transformation pathway and the rates of transformation should be determined in accordance with the test method. For the identification of potential metabolites 20 °C shall be used.'*

121. In the Notice of Appeal, the Appellants stated that the kinetic part of the study and the metabolite identification part of the study should both be performed at 12 °C. Later in the proceedings the Appellants state that both parts of the study should be performed at either 20 °C or 12 °C. However, at the hearing, the Appellants clarified that they were contesting the requirement to identify potential metabolites at 20 °C and request that the two parts of the test should be conducted at 12 °C.

122. Unlike the two parameters discussed in Sections 2.1.1. and 2.1.2. above, the requirement to perform the kinetic part of the study under aerobic conditions at a constant temperature of 12 °C and to use 20 °C for the identification of potential metabolites is expressed in mandatory terms in the Contested Decision.

123. According to paragraphs 31 and 32 of OECD TG 307, which address the test temperature:

'*During the whole test period, the soils should be incubated in the dark at a constant temperature representative of the climatic conditions where use or release will occur. A temperature of 20 ± 2 °C is recommended for all test substances which may reach the soil in temperate climates. The temperature should be monitored.*

For chemicals applied or released in colder climates (e.g. in northern countries, during autumn/winter periods), additional soil samples should be incubated but at a lower temperature (e.g. 10 ± 2 °C).'

124. In accordance with OECD TG 307 it is therefore possible to run the test at both 12 and 20 °C. OECD TG 307 does not however indicate that the kinetic and metabolite identification parts of the same test can be conducted at different temperatures.

125. The reasons for the choice of 12 °C for the kinetic part of the study are set out in the Contested Decision:

'*The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment […], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (Version 3.0 October 2016) indicates 12 °C as the average environmental temperature for the EU (for each compartment including soil).'*

126. The Contested Decision does not, however, provide any justification for performing the two parts of the test at different temperatures.

127. The Agency stated during these proceedings that the advantage of conducting the soil simulation testing at 20 °C rather than 12 °C is that there would be an increased possibility of degradation products being created at high enough concentrations to be identifiable. This is necessary because of the potentially slow formation of transformation products.

128. However, it must be noted that, for the same reason, the Appellants are also required to perform the test '*at least for 6 months (longer if possible), to give sufficient time for any transformation product to appear, unless it can already be concluded after a test duration of 4 months that the substance will meet the P- or vP criterion*'. Furthermore, again for the same reason, the Contested Decision states that '*transformation products formed at levels of 1 % or more of the test substance shall be [assessed], with reasonable attempts made to quantify these down to 0.1 %'* (see Section 2.1.2. above). The Contested Decision therefore sets out three separate specifications aimed at increasing the possibility of transformation and/or degradation products being identifiable at the end of the study.

129. In view of the above, the requirement to perform the two parts of the soil simulation testing at different temperatures exceeds the limits of what is appropriate and necessary and is therefore disproportionate.

130. The requirement to use 20 °C for the identification of potential metabolites is therefore annulled. Both parts of the test should therefore be performed at 12 °C.

2.2. Breach of the duty to state reasons

Arguments of the Appellants

131. The Appellants argue that the Agency failed to adequately state reasons for the request to perform soil simulation testing as required by Article 296 of the Treaty on the Functioning of the European Union and Article 130 of the REACH Regulation.

132. The Appellants argue that the Contested Decision contains insufficient justification that (i) there is a potential risk and (ii) for the non-standard testing parameters.

Arguments of the Agency and the eMSCA

133. The Agency, supported by the eMSCA, argues that the Appellants' plea is not substantiated. Furthermore, the Contested Decision contains sufficient information to allow the Appellants to understand why additional information is requested. The Appellants rather interpret the available data differently from the Agency.

Findings of the Board of Appeal

134. As stated in paragraphs 69 to 72 above, during the course of the present appeal the Appellants clarified that, in relation to the soil simulation testing, they were contesting only the additional testing parameters set out in the Contested Decision (see paragraph 74 above). Furthermore, the requirement to use 20 °C for the identification of potential metabolites has been annulled (see paragraphs 120 to 130 above). It is in this context that the Board of Appeal will examine whether the Agency breached the duty to state reasons.

135. A statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the Board of Appeal and the European Union judicature to exercise its power of review (see by analogy judgment of 21 December 2016, C*lub Hotel Loutraki and Others* v *Commission*, C-131/15 P, EU:C:2016:989, paragraph 46). Whether a statement of reasons is adequate depends on all the circumstances of a case, in particular, the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations (see judgment of 10 March 2016, *HeidelbergCement* v *Commission*, C-247/14 P, EU:C:2016:149, paragraph 16).

136. Section III(2) of the Contested Decision ('*Statement of Reasons*') provides reasons for requesting the soil simulation testing. In that Section the Agency also addresses the Appellants' arguments raised in their comments on the proposals for amendment, regarding the extraction techniques to be employed to extract the non-irreversibly bound fraction of the Substance, and the quantification of the transformation products down to 0.1 %. As demonstrated in Sections 2.1.1. to 2.1.3. above, the statement of reasons put forward in the Contested Decision is sufficient for the Appellants to understand and challenge the reasons for the additional test requirements and for the Board of Appeal to review those reasons.

137. The Appellants, however, disagree with the conclusions reached by the Agency regarding the parameters to be used in the test. In this respect, the duty to state reasons is different from the correctness of those reasons. The duty to state reasons is an essential procedural requirement which must be distinguished from the question whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue (judgment of 14 October 2010, *Deutsche Telekom* v *Commission,* C-280/08 P, EU:C:2010:603, paragraph 130; Case A-006-2012, *Momentive Specialty Chemicals*, Decision of the Board of Appeal of 13 February 2014, paragraph 113).

138. Whether the Agency made an error of assessment regarding the contested testing parameters has been examined in Section 2.1. above. In addition, it is not necessary for the Agency's reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons for a measure satisfies the duty to state reasons must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question. In particular, the Agency is not required to adopt a position on all the arguments relied on by the parties concerned, but it is sufficient if it sets out the facts and the legal considerations having decisive importance in the context of the decision (see judgment of 30 April 2014, *Hagenmeyer and Hahn* v *Commission*, T-17/12, EU:T:2014:234, paragraph 173). In the present case the Contested Decision addresses the relevant arguments raised by the Appellants during the decision-making procedure (see Sections 2.1.1. to 2.1.3. above). Furthermore, the Appellants did not claim that their arguments made during the decision-making procedure were not addressed by the Agency.

139. In view of the above, the Appellants' plea regarding a breach of the duty to state reasons is rejected.

2.3. Breach of procedural rights through the Agency's choice of procedure for requesting the soil simulation testing

Arguments of the Appellants

140. The Appellants argue that the Agency breached the procedural requirements of the REACH Regulation as the soil simulation study should have been requested under the compliance check procedure, and therefore without the non-standard requirements for strong extraction techniques, identification of metabolites down to 0.1 % and testing at 20 °C.

141. The Appellants argue that, in view of the non-standard testing parameters, the soil simulation testing requested in the Contested Decision cannot be considered standard information within the meaning of the Annexes to the REACH Regulation.

Arguments of the Agency

142. The Agency argues that substance evaluation was the correct choice of procedure for requesting the soil simulation study.

Findings of the Board of Appeal

143. In the present appeal the Appellants are not contesting the potential risk identified by the Agency to support the request for soil simulation testing (see paragraphs 69 to 72 above). The Appellants have not argued that their rights were infringed by the Agency's choice of procedure, for example with regards to the right to be heard or in relation to cost sharing. The Appellants contest rather the non-standard testing parameters applied to the soil simulation testing in the Contested Decision (see paragraph 74 above). In this respect, it is sufficient to note that the requirement to perform the identification of metabolites part of the test at 20 °C has been annulled (see Section 2.1.3. above). In addition, the Board of Appeal has found that the other two contested testing parameters are not mandatory (see Sections 2.1.1. and 2.1.2. above). It is therefore no longer necessary for the Board of Appeal to examine the Appellants' plea regarding the Agency's choice of procedure for requesting the soil simulation testing.

Claim for the reimbursement of costs

144. In its Notice of Appeal the Appellants requested the Board of Appeal to order the Agency to pay the costs of these proceedings.

145. 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, the 'Rules of Procedure'), as amended by Commission Implementing Regulation (EU) 2016/823 (OJ L 137, 26.5.2016, p. 4), does not make provision for the

reimbursement of costs that are not, as provided in Articles 17 and 21(1)(h) thereof, related to the taking of evidence. Furthermore, Article 17a of the Rules of Procedure provides that the parties shall bear their own costs.

146. Consequently, and as in the present case no costs arose in relation to the taking of evidence, the Appellants' request for reimbursement of costs is rejected.

Refund of the appeal fee

147. 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.

148. As the appeal has been partially decided in favour of the Appellants, the appeal fee must be refunded.

Effects of the Contested Decision

149. According to Article 91(2), an appeal has suspensive effect.

150. The Contested Decision required the Appellants to provide the information on soil simulation testing by 1 July 2019, which is two years, three months and eight days from the date of its notification.

151. The Appellants must therefore provide the information on the soil simulation testing by 4 January 2021.

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. **Dismisses the appeal as regards the requirement to provide information on soil simulation testing with the exception of the requirement to use 20 °C during the test for the identification of potential metabolites which is annulled. The kinetic and metabolite identification parts of the soil simulation testing should both be performed at 12 °C.**
4. **Decides that information on soil simulation testing must be submitted by 4 January 2021.**
5. **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