EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

6 June 2018

(Substance evaluation of a monomer – Article 46 – Article 2(9) – Monomer as an unreacted impurity in polymers – Monomer as a degradation product of polymers – Proportionality – Legal certainty – Predicted No-Effect Concentration – Species Sensitivity Distribution model)

Case number	A-006-2016
Language of the case	English
Appellants	SI Group UK Ltd, United Kingdom TÜV SÜD Iberia S.A.U., Spain Sasol Germany GmbH, Germany Nalco Limited, United Kingdom Oy Nizhex Scandinavia Ltd, Finland Addivant UK Ltd, United Kingdom MHM Holding GmbH, Germany PCC Synteza SA, Poland ICC Industries BV, the Netherlands Hermes Chemicals Marketing B.V., the Netherlands GE Water & Process Technologies bvba, Belgium GE Water & Process Technologies France SAS, France
Representative	Marcus Navin-Jones Keller and Heckman LLP, Belgium
Intervener	Health and Safety Executive, United Kingdom Represented by: Steve Dungey Environment Agency, United Kingdom
Contested Decision	Decision of 29 April 2016 on the substance evaluation of phenol, 4-nonyl-, branched, adopted by the European Chemicals Agency (the '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 Rapporteur) and Sari Haukka (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. The Appellants are registrants of the substance phenol, 4-nonyl-, branched (CAS No 84852-15-3, EC No 284-325-5; 'nonylphenol').

2. Nonylphenol is a monomer used in the manufacture of polymers, including nonylphenol ethoxylates ('NPEO') and phenol/formaldehyde resins. It is registered cumulatively in quantities of 10 000 to 100 000 tonnes *per annum*.

3. Nonylphenol is a priority hazardous substance under Annex X to Directive 2000/60/EC establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1; the 'Water Framework Directive'). Due to its environmental endocrine disrupting properties, it has also been identified as a substance of very high concern ('SVHC') under Article 59 of the REACH Regulation (all references to Recitals, Titles, Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise). Nonylphenol is subject to specific restrictions on its manufacture, marketing and use under Annex XVII.

4. NPEO is subject to specific restrictions on its manufacture, marketing and use under Annex XVII (see Commission Regulation (EU) 2016/26 amending Annex XVII as regards NPEO, OJ L 9, 14.1.2016, p. 1). NPEO is also subject to authorisation under Annex XIV, with a '*sunset date*' of 4 January 2021, because of the effects of its degradation products which include nonylphenol.

5. Nonylphenol was included in the Community Rolling Action Plan ('CoRAP') for substance evaluation due to initial grounds for concern relating to its potential persistent, bioaccumulative and toxic ('PBT') properties, and potential environmental exposure.

6. The Health and Safety Executive ('HSE') was appointed to carry out the substance evaluation of nonylphenol as Member State Competent Authority of the United Kingdom.

7. On 7 May 2015, a draft decision prepared by HSE requesting further information pursuant to Article 46(1) was notified to the registrants of nonylphenol in accordance with Article 50(1).

8. By 15 June 2015, the registrants provided comments on the draft decision to the Agency.

9. HSE considered the registrants' comments and notified a revised version of the draft decision to the competent authorities of the other Member States and the Agency.

10. Two competent authorities and the Agency submitted proposals for amendment pursuant to Article 51(2) in conjunction with Article 52(2). HSE reviewed the proposals for amendment and further amended the draft decision.

11. By 4 January 2016, the registrants commented on the proposals for amendment.

12. On 2 to 4 February 2016, the Member State Committee considered the amended draft decision and the registrants' comments on the proposals for amendment and reached unanimous agreement on a modified version of the amended draft decision.

13. On 29 April 2016, the Agency adopted the Contested Decision.

Contested Decision

14. The Contested Decision requires the Appellants to submit further information on nonylphenol by 6 November 2017.

15. Part B of Section II of the Contested Decision states:

`*Information for environmental exposure assessment*

Pursuant to Article 46(1) […] the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision:

[2] Information on the annual tonnage of the registered substance manufactured and placed on the market by each Registrant for each of the Exposure Scenarios (ES) in the Chemical Safety Report (CSR), and also the annual supply tonnage of individual polymers (e.g. resins, nonylphenol ethoxylates (NPEOs), etc.) (which can be grouped if justified) that are placed on the EU market by the Registrant(s) and their downstream users, broken down by use (estimated if necessary). This information can be provided separately by each Registrant or downstream user if it is commercially sensitive. If the Registrant(s) are unable to gather suitably representative data for any part of the life cycle, they shall base their assessment of that life cycle stage on reasonable worst case assumptions (with justification).

[3] Information on the typical concentration of the registered substance as an unreacted impurity in polymers and the potential for its formation from the polymers during environmental degradation. This information can be provided separately by each Registrant or downstream user if it is commercially sensitive. Following an assessment of relevance, Exposure Scenarios (ES) shall be produced for significant sources. If the Registrant(s) are unable to gather suitably representative data for any part of the life cycle, they shall base their assessment of that life cycle stage on reasonable worst case assumptions (with justification).

[4] Justification as to why Exposure Scenarios involving NPEO do not take account of the further degradation of NPEO released in Waste Water Treatment Plant (WWTP) effluent to the registered substance.

[5] Justification as to why registration dossiers do not include ES15 (Service life of paints containing NPEO) as a relevant use when they include ES9 (Formulation of paints containing NPEO).

[6] An update of all Exposure Scenarios (ES) to include the waste phase or justification as to why it is not relevant. This should include all lifecycle steps, including production/formulation/ processing and disposal of products containing the registered substance (or polymers) at the end of their service life.'

16. Part D of Section II of the Contested Decision is worded as follows:

`*Information for environmental [Predicted No-Effect Concentration, 'PNEC']*

Unless the Registrant(s) conclude that the registered substance meets the [PBT] criteria, requests concerning the environmental PNECs (10-15) are required.

Pursuant to Article 46(1) […] the Registrant(s) shall submit the following information using the indicated test methods/instructions (in accordance with Article 13 (3) and (4) […]) and the registered substance subject to the present decision:

[10] Derivation of a long-term NOEC [No Observed Effect Concentration] / EC10 [10% Effect Concentration] for the registered substance with Rainbow Trout Oncorhynchus mykiss, taking account of transgenerational effects as described

by Schwaiger et al. (2002) […] and the Risk Assessment Committee opinion (ECHA, 2014c).

[11] An estimated chronic NOEC for Winter Flounder Pleuronectes americanus based on the reported 96-h LC50 of 17 µg/L from Lussier et al. (2000) and the worst case acute: chronic ratio from other fish species in the aquatic toxicity data set.

[12] Long-term toxicity testing of the registered substance on aquatic molluscs:

a. A reproduction study with the freshwater gastropod Potamopyrgus antipodarum in accordance with the OECD mollusc reproduction test guideline approved in April 2016 (the latest protocol of the draft guideline can be found at this link: http://www.oecd.org/env/ehs/testing/Potamopyrgus%20for%202nd%20WNT%20comments_clean.pdf).

b. A life cycle study with the marine bivalve Crassostrea gigas in accordance with the method of Nice et al. (2003) […]. An oyster embryo-larval toxicity test […] may be performed to help with range finding, in accordance with an appropriate standard method (e.g. CES TIMES No 54 […] or US EPA OPTTS 850.1055 […]).

[13] Long-term toxicity testing of the registered substance on echinoderms. In the absence of an EU standard method, the study shall be conducted in accordance with a suitable national standard method (e.g. Environment Canada Biological test method EPS 1/RM/27 12). The Registrant(s) shall justify the choice of test species based on an assessment of the most sensitive species from studies reported in the scientific literature.

For tests 12 and 13, a study must be performed if a reliable chronic NOEC/EC 10 for reproduction and growth for these species cannot be derived from published studies in the literature, as specified in [the Section of the Contested Decision entitled 'Statement of reasons'].

[14] Revision of the $PNEC_{water}$ for both fresh and marine surface waters (combined if relevant) once the Registrant(s) have provided the information for requests 10-13. This shall include specifying the end point and species choice (in terms of taxonomic coverage), a description of relevant summary statistics for the species sensitivity distribution (if derived) to justify the choice of model in accordance with ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.10, May 2008), and choice of assessment factor to apply to the HC5, together with a discussion about the suitability of the approach for any apparently sensitive trophic groups or species.

[15] Assessment of all available information to address avian toxicity of the registered substance using the Integrated Testing Strategy (ITS) provided in section 7.10.19 in ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.7c, version 2, November 2014) and observations whether avian testing is needed to address any remaining risks.'

Procedure before the Board of Appeal

17. On 28 July 2016, the Appellants filed this appeal.

18. On 3 October 2016, the Agency submitted its Defence.

19. On 14 December 2016, the Appellants submitted their observations on the Defence.

20. On 19 January 2017, HSE was granted leave to intervene in this case in support of the Agency.

21. On 14 February 2017, the Agency submitted its observations on the Appellants' observations on the Defence.

22. On 14 March 2017, HSE submitted its statement in intervention.

23. On 4 April 2017, the Appellants and the Agency submitted their observations on the statement in intervention.

24. On 10 and 16 August 2017 respectively, the Appellants and the Agency replied to written questions from the Board of Appeal.

25. On 22 November 2017, 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

26. The Appellants request the Board of Appeal to:

- declare the appeal admissible and well-founded,
- annul Parts B and D of Section II of the Contested Decision,
- take any other measures as justice may require, and
- order the '*reimbursement of costs incurred by the Appellants in these appeal proceedings, and/or [the] refund of the appeal fee*'.

27. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal as partially inadmissible and partially unfounded, or, in any event, as entirely unfounded.

Reasons

1. Admissibility

28. The Agency argues that GE Water & Process Technologies bvba and GE Water & Process Technologies France SAS are neither addressees of the Contested Decision nor directly and individually concerned by it. They are therefore not entitled to bring an appeal against the Contested Decision.

29. However, when several appellants bring a single appeal, and it is found that the bringing of the appeal by one appellant is admissible, there is no need to consider whether the other appellants are entitled to bring proceedings (see, by analogy, judgment of 22 April 2015, *Tomana and Others* v *Council and Commission,* T-190/12, EU:T:2015:222, paragraph 72; see also Case A-011-2014, *Huntsman P&A UK and Others*, Decision of the Board of Appeal of 2 March 2017, paragraph 28).

30. All Appellants are challenging the same Contested Decision by a single appeal. The appeal is clearly admissible in so far as it has been filed by Appellants who are addressees of the Contested Decision.

31. There is consequently no need to consider whether GE Water & Process Technologies bvba and GE Water & Process Technologies France SAS are entitled to bring proceedings individually.

2. Substance

32. The challenged parts of the Contested Decision cover three distinct areas:

- requests for information from registrants and downstream users to improve the environmental exposure assessment (Part B of Section II of the Contested Decision, paragraph 15 above),

- information from registrants to improve the accuracy and reliability of the PNEC (Part D of Section II of the Contested Decision, paragraph 16 above), and
- the deadline for providing this information.

33. In order to address the Appellants' numerous pleas and arguments relating to these three distinct areas, the present decision is structured in the following way:

2.1. Whether information on polymers can, in principle, be requested in a substance evaluation decision on a monomer.

2.2. Whether the information requirements in Part B of Section II of the Contested Decision are lawful. In particular:

2.2.1. The obligation to submit to the Agency information that is to be obtained from the Appellants' downstream users or, alternatively, make '*reasonable worst case assumptions*'.

2.2.2. The obligation to submit to the Agency information that the Appellants already possess or can generate themselves.

2.3. Whether the information requirements in Part D of Section II of the Contested Decision are lawful.

2.4. Whether the deadline in the Contested Decision is too short.

2.1. Whether information on polymers can, in principle, be requested in a substance evaluation decision on a monomer

Arguments of the Appellants

34. The Appellants argue that the Agency does not have the power to request information on the polymers derived from nonylphenol because polymers are exempted from the registration and evaluation requirements in the REACH Regulation. The fact that some available information on polymers derived from nonylphenol was included in the Appellants' chemical safety reports ('CSRs') does not alter this conclusion as this information was submitted purely on a voluntary basis.

35. By requiring information on polymers, the Agency therefore breached Articles 2(9) and 46, contravened the '*legal intent*' of substance evaluation, and committed an error of assessment.

36. In the alternative, the Appellants claim that, if the requested information is considered to be standard information that must be contained in the CSRs, such information must be requested through the dossier evaluation procedure and not through the substance evaluation procedure.

Arguments of the Agency and the Intervener

37. The Agency, supported by HSE, argues that it has the power to request the information at issue. Although polymers are exempted from registration and evaluation, they are not excluded altogether from the scope of the REACH Regulation.

38. First, according to the Agency, the Contested Decision follows the evaluation of nonylphenol and requests information on the entire life-cycle of nonylphenol, including its presence in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers. The Contested Decision is not the result of the evaluation of one or more polymers.

39. Second, a registrant of a monomer must address the uses of that monomer in its chemical safety assessment ('CSA'), including the exposure assessment and risk

characterisation steps. As a CSA must cover the entire life-cycle of the registered substance, in the case of nonylphenol, it must address the risks arising from the presence of that substance as an unreacted impurity in polymers and as a degradation product from those polymers. The Agency argues that this is borne out by paragraphs 51 to 53 of the judgment of the Court of Justice of 7 July 2009 in Case C-558/07, *S.P.C.M. and Others*, EU:C:2009:430.

Findings of the Board of Appeal

40. The Contested Decision requires, amongst other things, information concerning the presence of nonylphenol in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers (see paragraph 15 above).

41. The Appellants argue that this request exceeds the powers of the Agency under Article 46 in conjunction with Article 2(9).

42. At the outset, it must be noted that a monomer ceases to be a monomer upon polymerisation, and becomes a different substance within the meaning of Article 3(1), namely a polymer (see, to this effect, judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 34; see also the Opinion of Advocate General Kokott in that case, EU:C:2009:142, paragraph 48).

43. In order to decide on the Appellants' argument, the Board of Appeal will therefore examine whether the Agency can request information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, pursuant to the substance evaluation of a monomer despite the fact that monomers and polymers are different substances within the meaning of Article 3(1) (Section 2.1.1. below) and that polymers are exempted from registration and evaluation pursuant to Article 2(9) (Section 2.1.2. below).

2.1.1. Whether a request for further information on a monomer under Article 46 may extend to information on the presence of that monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers

44. Under Article 46, the Agency may require '*further information […], including, if appropriate, information not required in Annexes VII to X*'. It may do so in order to clarify a potential risk to human health and the environment (see, to this effect Case A-023-2015, *Akzo Nobel and Others*, Decision of the Board of Appeal of 13 December 2017, paragraph 40, and Case A-015-2015, *Evonik Degussa and Others*, Decision of the Board of Appeal of 30 June 2017, paragraph 87).

45. When interpreting a provision of European Union law its wording and, if necessary, its context and objectives must all be taken into account (see judgment of 21 January 2016, *Knauer*, C-453/14, EU:C:2016:37, paragraph 27, and judgment of 16 December 2015, *Sweden* v *Commission*, T-521/14, EU:T:2015:976, paragraph 59).

46. The Board of Appeal will therefore examine the wording and, if necessary, the context and objectives of Article 46, and the objectives of the REACH Regulation as a whole.

47. As regards its wording, Article 46 does not expressly state whether a request for further exposure information may or may not extend to a substance other than the monomer under evaluation. Article 46 however does mention the possibility of requesting, '*if appropriate*', information that goes beyond the information required for registration purposes.

48. As regards the context of Article 46, nothing in Chapter 2 ('*Substance Evaluation*') of Title VI ('*Evaluation*'), or elsewhere in the REACH Regulation, addresses the issue of whether under substance evaluation a request for further information on a monomer may extend to a substance other than the monomer under evaluation.

49. Recital 66 states, in the broadest terms, that '*[t]he Agency should also be empowered to require further information […] on substances suspected of posing a risk to human health and the environment […] on the basis of evaluations performed*'.

50. A monomer can pose a risk to human health and the environment by reason of its presence as an unreacted impurity in another substance, namely a polymer, or because it is the transformation or degradation product of that other substance. For example, in the present case, there may be environmental exposure to nonylphenol by reason of its presence as an unreacted impurity in polymers and/or as a degradation product from those polymers. The risk arising from such exposure can constitute grounds for establishing regulatory risk management measures for the monomer in question, for instance under Titles VII (Authorisation) and VIII (Restrictions).

51. The objective of Article 46 is to allow the Agency to require further information in order to clarify any risk arising from the use of a substance. This is essential in order to attain the main objective of the REACH Regulation, which is to achieve a high level of protection of human health and the environment (judgment of 25 September 2015, *PPG and SNF* v *ECHA*, T-268/10 RENV, EU:T:2015:698, paragraph 83).

52. An interpretation of Article 46 according to which no information, however necessary to the evaluation of the risks posed by a monomer, can be requested on the presence of that monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, would contradict that objective.

53. It follows that Article 46 must be interpreted as meaning that a request for further information on a monomer may extend to information on the presence of that monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

2.1.2. Whether Article 2(9) prevents the Agency from requesting information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers

54. The Contested Decision requires information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers. It must be examined whether Article 2(9) prevents this.

55. When interpreting a provision of European Union law its wording and, if necessary, its context and objectives must all be taken into account (see paragraph 45 above).

56. The Board of Appeal will therefore examine the wording and, if necessary, the context and objectives of Article 2(9), and of the REACH Regulation as a whole.

- Wording of Article 2(9)

57. In accordance with Article 2(9), '*[t]he provisions of Titles II ["Registration"] and VI ["Evaluation"] shall not apply to polymers*'.

58. It is clear from the phrase '*shall not apply to polymers*' that, as the REACH Regulation currently stands, manufacturers or importers of polymers are not required to register those polymers, and polymers cannot be subject to dossier or substance evaluation.

59. In the present case, polymers are not being made subject to registration nor is an evaluation being conducted on polymers.

60. However, Article 2(9) does not expressly state whether the Agency can require information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

61. The Board of Appeal will therefore examine the context and objectives of Article 2(9), and also the objectives of the REACH Regulation as a whole.

- Context of Article 2(9)

62. The REACH Regulation provides that, in principle, all substances that are manufactured or imported in the European Union in quantities above one tonne per year must be registered and may be evaluated.

63. Article 2(9) constitutes an exception to this rule as regards polymers (see, to this effect, *S.P.C.M. and Others*, cited in paragraph 42 above, paragraphs 29 to 31).

64. As it is an exception, Article 2(9) must be interpreted strictly (judgment of 27 September 2017, *Puškár*, C-73/16, EU:C:2017:725, paragraph 38).

65. The Appellants propose an interpretation of Article 2(9) according to which no information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, can be requested pursuant to substance evaluation. However, this would not be a strict interpretation. On the contrary, it would expand the scope of the exception by exempting from evaluation not only polymers *per se*, but also preventing any information requests on polymers following the evaluation of a monomer.

66. The context of Article 2(9) therefore suggests that this provision does not prevent the Agency from requiring information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

- Objectives of Article 2(9)

67. Recital 41 states:

'*Polymers should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria*' (emphasis added).

68. The explanatory memorandum to the European Commission's proposal for the REACH Regulation (COM/2003/0644 final) states in this regard:

'*Polymers have been exempted from registration and evaluation, but may still be subject to authorisation and restriction. […] In view of the potentially large number of polymer registrations and given that most of them pose a limited risk because of their nature, polymers are exempted from registration for reasons of workability, and to focus resources on substances of more concern. […] Since polymers are exempted from registration, they are also exempted from evaluation*' (emphasis added).

69. It is clear from the above that the objective of the exemption of polymers from the obligation to register is to avoid imposing an excessive burden on the manufacturers and importers of polymers, as well as on the Agency and the Member States, whilst ensuring that risks arising from polymers can still be controlled. The objective of the exemption is not to exclude polymers from the scope of the REACH Regulation altogether.

70. It is equally clear from the above that the exemption of polymers from (dossier and substance) evaluation is simply the consequence of their exemption from the obligation to register. Indeed, as long as polymers are not registered there are no dossiers to evaluate, and no evaluation of those polymers on the basis of a registration is therefore possible.

71. A request for information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, is limited and substantially less burdensome than an obligation to submit a registration for those polymers.

72. The objectives of Article 2(9) therefore suggest that this provision does not prevent the Agency from requiring information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

- Objectives of the REACH Regulation

73. In accordance with Article 1(1), the purpose of the REACH Regulation '*is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation*'.

74. In particular, according to case-law, achieving a high level of protection of human health and the environment is the main objective of the REACH Regulation (see *PPG and SNF* v *ECHA*, cited in paragraph 51 above, paragraph 83).

75. An interpretation of Article 2(9) according to which the Agency may require information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, contributes to achieving this objective.

76. Human and environmental exposure to monomers can be the result of the use of polymers as well as their manufacture. For example, exposure to nonylphenol may occur due to the presence of nonylphenol as a degradation product of NPEO (see paragraph 4 above).

77. Consequently, in order to ensure that the risks arising from the use of a monomer can be properly evaluated, the Agency must have the possibility of obtaining information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, pursuant to the substance evaluation of a monomer. Any interpretation to the contrary would defeat the main objective of the REACH Regulation with regard to protecting human health and the environment from the risks posed by, in the context of this case, monomers.

78. Moreover, Article 2(9) exempts polymers only from Titles II (Registration) and VI (Evaluation). Polymers are not excluded from the scope of application of the REACH Regulation altogether. In particular, polymers are not exempted from Titles VII (Authorisation) and VIII (Restrictions). Information on the presence of a monomer in polymers as an unreacted residue after polymerisation, or as a degradation product of those polymers can contribute to protecting human health and the environment from risks posed by polymers which are subject to, for example, authorisation(s) or restriction(s).

79. In addition, Article 1(3) states that the provisions of the REACH Regulation are underpinned by the precautionary principle.

80. The precautionary principle is a general principle of European Union law requiring authorities, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests (see judgment of 21 October 2003, *Solvay Pharmaceuticals* v *Council*, T-392/02, EU:T:2003:277, paragraph 121; judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, EU:T:2013:167, paragraph 134; see also, to that effect, judgment of 26 November 2002, *Artegodan and Others* v *Commission*, T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, EU:T:2002:283, paragraphs 183 and 184).

81. Where there is scientific uncertainty as to the existence or extent of risks to human health or to the environment, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent or until the adverse effects materialise (see, to this effect, judgment of 10 April 2014, *Acino* v *Commission*, C-269/13 P, EU:C:2014:255, paragraph 57 and the case-law cited; see also *Du Pont de Nemours (France) and Others* v *Commission*, cited in the previous paragraph, paragraph 135, and judgment of 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, EU:T:2013:407, paragraph 44).

82. An interpretation of Article 2(9) according to which the Agency may require information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, is fully consistent with the precautionary principle. There may be grounds to suspect that a monomer may pose a potential risk to human health or the environment because of its presence in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers. In this case, the Agency must be able to clarify that potential risk so that protective measures can eventually be adopted with regard to that monomer or its uses in the manufacture of polymers.

83. It is therefore consistent with the objectives of the REACH Regulation to interpret Article 2(9) as not preventing the Agency from requiring information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

2.1.3. Conclusion

84. The Contested Decision was adopted pursuant to the substance evaluation of nonylphenol, a monomer. The Contested Decision was not adopted following the substance evaluation of a polymer.

85. For the reasons set out above, Article 2(9) in conjunction with Article 46 must be interpreted as meaning that the Agency has the power to request information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, pursuant to the substance evaluation of a monomer.

86. The Contested Decision consequently does not exceed the Agency's power insofar as it requires information on the presence of nonylphenol in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

87. The Appellants' arguments to that effect must therefore be rejected.

2.2. Part B of Section II of the Contested Decision (information requirements 2 to 6)

88. Information requirements 2 to 6 (see paragraph 15 above) require the Appellants, in essence, to do two things.

89. First, the Appellants must obtain from their downstream users, and submit to the Agency, information on the presence of nonylphenol in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers. If the Appellants are unable to obtain this information from their downstream users, according to information requirements 2 and 3, they may make '*reasonable worst case assumptions*' on the potential for environmental exposure of nonylphenol through those polymers. These obligations are addressed in Section 2.2.1. below.

90. Second, the Appellants must submit to the Agency information on polymers derived from nonylphenol, and on nonylphenol itself, that they already have or can generate themselves (information requirements 2 to 6). These obligations are addressed in Section 2.2.2. below.

2.2.1. Information to be obtained from downstream users or, alternatively, '*reasonable worst case assumptions*'

Arguments of the Appellants

91. The Appellants claim that information requirements 2 to 6 breach the principles of legal certainty and proportionality insofar as they require the Appellants to obtain information from their downstream users or, alternatively, make '*reasonable worst case assumptions*'.

92. First, the Appellants argue that they have no means to force those downstream users to provide the information. The requests therefore expose the Appellants to a risk of enforcement action as compliance with the Contested Decision is outside their control.

93. Second, with regard to the alternative obligation to make '*reasonable worst case assumptions*' if they are unable to obtain the information at issue from their downstream users (information requirements 2 and 3), the Appellants argue that it is unclear how to interpret '*reasonable worst case assumptions*' in this case.

Arguments of the Agency and the Intervener

94. The Agency, supported by HSE, argues that requiring the Appellants to obtain information from their downstream users or, alternatively, make '*reasonable worst case assumptions*' is the only suitable way to clarify whether and how nonylphenol is released into the environment because it is present in polymers. The identity of downstream users is known to the Appellants but not to the Agency or the competent authorities of the Member States.

95. The Agency further argues that the Appellants' downstream users are obliged to provide to the Appellants the information at issue, which is standard information for the registration of nonylphenol. If they refuse to do so, the relevant uses should be removed from the registration, thereby obliging the downstream users to submit their own downstream user reports in accordance with Article 37.

96. Moreover, according to the Agency, the Contested Decision does not oblige the Appellants to achieve impossible results. If the Appellants cannot obtain certain information from their downstream users, they may make their assessments based on '*reasonable worst case assumptions*'.

Findings of the Board of Appeal

97. Article 46 empowers the Agency to require registrants to submit further information in order to clarify a potential risk to human health or the environment posed by a substance (see paragraph 44 above).

98. Such information requirements can potentially be broad and require not only the collection and submission of information available to the addressees of a decision, but also the collection, generation and submission of new information.

99. However, the exercise of this prerogative by the Agency is inherently subject to a number of conditions. These conditions include respecting the principles of proportionality and legal certainty.

100. The principle of proportionality requires that a measure must, amongst other things, be capable of achieving its objective (see, to this effect, judgment of 17 March 2016, *Zoofachhandel Züpke and Others* v *Commission*, EU:T:2016:157, paragraph 50 and the case-law cited). The principle of legal certainty requires, amongst other things, that European Union legislation must be applied – for example through a substance evaluation decision – in a way that is foreseeable by those subject to it (see, to this effect, judgment of 14 October 2010, *Nuova Agricast and Cofra* v *Commission*, C-67/09 P, EU:C:2010:607, paragraph 77, and judgment of 16 July 2014, *National Iranian Oil Company* v *Council*, T-578/12, EU:T:2014:678, paragraphs 111 and 112).

101. If it is impossible to obtain the information required by a substance evaluation decision, firstly, its objective cannot be met and, secondly, there is no legal certainty with regard to its consequences for the addressees of that decision.

102. The principles of proportionality and legal certainty therefore require that a substance evaluation decision cannot oblige registrants to provide information which they can neither assuredly obtain nor generate themselves.

103. It must now be determined whether the obligation to submit to the Agency information that must be obtained from the Appellants' downstream users, and the alternative obligation to submit information based on '*reasonable worst case assumptions*', comply with the requirements set out in the previous paragraph.

2.2.1.1. Information to be obtained from downstream users

104. There is no provision in the REACH Regulation that would allow the Appellants to oblige their downstream users to provide them with the information required on the presence of nonylphenol in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

105. Even assuming that the information at issue would be standard information for the registration of nonylphenol, downstream users would, at most, be obliged to do one of two things.

106. First, in accordance with Article 37(2), downstream users could provide to the Appellants '*sufficient information to allow [them] to prepare an exposure scenario or, if appropriate, a use and exposure category, for [the use of the downstream user] in the [registrants'] chemical safety assessment*'.

107. Second, in accordance with Article 37(4), downstream users could prepare and submit to the Agency their own chemical safety report '*for any use outside the conditions described in an exposure scenario*' (see Case A-022-2015, *Manufacture Française des Pneumatiques Michelin*, Decision of the Board of Appeal of 30 May 2017, paragraphs 80 and 81.

108. In either event, the choice rests with the downstream users. The Appellants are not obliged to refuse to supply nonylphenol to their downstream users if those downstream users refuse to provide them with information on the presence of a monomer in their polymers, or do not submit to the Agency their own downstream user reports containing that information.

109. The Appellants therefore have no means, under the REACH Regulation, to oblige their downstream users to provide them with information on the presence of nonylphenol in their polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers.

110. Information requirements 2 to 6 therefore breach the principles of legal certainty and proportionality insofar as they oblige the Appellants to obtain from their downstream users and submit to the Agency information on the presence of nonylphenol in downstream users' polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers. They must therefore be annulled to this extent.

2.2.1.2. Reasonable worst case assumptions

111. Information requirements 2 and 3 provide that, if the Appellants are unable to obtain from their downstream users representative information for any part of the life-cycle of those downstream users' polymers, the Appellants '*shall base their assessment of that life cycle stage on reasonable worst case assumptions (with justification)*'.

112. The requirement for the Appellants to make '*reasonable worst case assumptions*' concerning their downstream users' polymers therefore depends on the requirement for the Appellants to obtain information from their downstream users.

113. The requirement for the Appellants to obtain information from their downstream users must be annulled for the reasons set out in paragraphs 104 to 110 above. Consequently, the requirement for the Appellants to make '*reasonable worst case assumptions*' concerning their downstream users' polymers must also be annulled.

2.2.1.3. Conclusion

114. In light of the above, information requirements 2 to 6 breach the principles of proportionality and legal certainty insofar as they require the Appellants to provide information on polymers that they do not themselves manufacture or import or, alternatively, make '*reasonable worst case assumptions*' regarding these polymers.

115. Information requirements 2 to 6 must consequently be annulled to this extent.

116. The reason for this annulment is that the way in which the Agency required the Appellants to provide the information at issue was not appropriate to achieve its objective, and legally uncertain. The present case should therefore be remitted to the competent body of the Agency for further action in this regard in accordance with Article 93(3).

2.2.2. Information that the Appellants already have or can generate themselves

Arguments of the Appellants

117. The Appellants argue that information requirements 2 to 6 (see paragraph 15 above) are disproportionate insofar as they require information on polymers derived from nonylphenol, and on nonylphenol itself, that the Appellants already have or can generate themselves. In particular:

- first, the Agency failed to establish a potential risk that would justify requiring further information for each polymer on which information is requested. For example, some polymers may not contain nonylphenol as an unreacted impurity after polymerisation or produce nonylphenol as a degradation product. The Appellants also argue that the Agency breached the duty to state reasons in this regard, and
- second, information requirements 2 to 6 are not appropriate to achieve their objective because they would force the Appellants to breach the rules on competition set out in Articles 101 and 102 of the Treaty on the Functioning of the European Union ('TFEU') by sharing sensitive information.

118. The Appellants further argue that information requirements 2 to 6 breach the principle of legal certainty because they are not clear and precise. In particular:

- first, the Contested Decision does not define the term '*individual polymer*',
- second, the Contested Decision does not specify whether the information requirements apply only to polymers that fall within the definition of a '*substance*' under the REACH Regulation,
- third, the Contested Decision does not specify whether the information requirements also apply to polymers in articles,
- fourth, although the Contested Decision allows individual polymers to be '*grouped*', it does not indicate what method of 'grouping' will be acceptable to the Agency,
- fifth, the Contested Decision does not define the term '*annual supply tonnage*' or set any *de minimis* limit for reporting purposes,
- sixth, with regard to information requirement 6 (update of all exposure scenarios to include the waste phase or justification as to why it is not relevant), the Appellants may not be able to provide the required information and it is unclear what the consequences of this would be,
- seventh, it is uncertain how the requested information is to be submitted to the Agency in practice, and
- eighth, it is unclear whether information requirement 5 ('*Justification as to why registration dossiers do not include ES15 [Service life of paints containing NPEO] as a relevant use*') applies to all Appellants or only to those who have included paint formulation as an exposure scenario.

Arguments of the Agency and the Intervener

119. The Agency, supported by the Intervener, disputes the Appellants' arguments.

120. First, according to the Agency, exposure information on the presence of nonylphenol in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, is necessary to ensure that the risk arising from the use of nonylphenol is properly managed. In particular:

- nonylphenol poses a considerable environmental hazard, and
- monitoring data show that nonylphenol continues to be widely emitted into the environment. This suggests that either the current risk management measures are ineffective or there are sources of nonylphenol, such as polymers, that are not reflected in the current registrations.

121. Second, according to the Agency, information requirements 2 to 6 do not require the Appellants to share information, thereby avoiding any potential breach of Article 101 or 102 of the TFEU. The Appellants may use a third party to collect and aggregate the data, or submit those data to the Agency individually.

122. The Agency further argues that information requirements 2 to 6 are clear and precise.

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123. In addition to submitting information to be obtained from their downstream users or by making '*reasonable worst case assumptions*' (addressed in Section 2.2.1. above), information requirements 2 to 6 also oblige the Appellants to provide certain information that the Appellants already have or could generate themselves (see paragraph 15 above).

124. The Appellants argue that these information requirements breach the principles of proportionality and legal certainty, albeit for reasons different to those examined in Section 2.2.1. above.

125. The Board of Appeal will examine the Appellants' arguments in the following order:

- whether the Agency failed to establish that further information on the presence of nonylphenol in polymers is necessary (Section 2.2.2.1. below),
- whether information requirements 2 to 6 are appropriate to achieve their objective insofar as they request information on polymers that the Appellants manufacture or import themselves (Section 2.2.2.2. below), and
- whether information requirements 2 to 6 respect the principle of legal certainty insofar as they request information on polymers that the Appellants manufacture or import themselves (Section 2.2.2.3. below).

2.2.2.1. Whether the Agency failed to establish that further information on the presence of nonylphenol in polymers is necessary

126. The Appellants do not dispute that nonylphenol poses a potential risk to human health and the environment due to its endocrine disrupting properties, that this potential risk needs to be clarified, or that the required information may lead to improved risk management measures.

127. Nevertheless, the Appellants argue that the Contested Decision fails to establish, and explain, the existence of a potential risk with regard to each individual polymer on which information is requested (see the first indent of paragraph 117 above).

128. The Board of Appeal notes that information requirements 2 to 6 arise from the evaluation of nonylphenol, not the evaluation of each individual polymer made from nonylphenol. The Agency is consequently not required to establish, or explain, the existence of a potential risk with regard to each individual polymer but only for nonylphenol.

129. The Appellants' argument that the Agency failed to establish, and explain, the existence of a potential risk with regard to each individual polymer on which information is requested must consequently be rejected.

2.2.2.2. Whether information requirements 2 to 6 are appropriate to achieve their objective insofar as they request information on polymers that the Appellants manufacture or import themselves

130. The Appellants argue that, by sharing the information required by information requirements 2 to 6 in order to submit it, they will be forced to breach Articles 101 and 102 of the TFEU (see the second indent of paragraph 117 above).

131. Information requirements 2 to 6 oblige the Appellants to submit to the Agency certain information on nonylphenol and on the polymers made from nonylphenol that they themselves manufacture or import. The Contested Decision gives the Appellants leeway as to how to do this. For example, the Appellants may submit this information individually, or they may make use of the services of a third party to gather, present and submit it.

132. Even if the information at issue were such that its sharing could lead to an infringement of Articles 101 or 102 of the TFEU, the Appellants can therefore comply with the requirements of both the Contested Decision and Articles 101 and 102 of the TFEU.

133. The Appellants' argument must consequently be rejected.

2.2.2.3. Whether information requirements 2 to 6 respect the principle of legal certainty insofar as they request information on polymers that the Appellants manufacture or import themselves

134. The Appellants argue that information requirements 2 to 6 breach the principle of legal certainty as regards information on the polymers that the Appellants manufacture or import themselves (see paragraph 118 above).

135. First, according to the Appellants, the Contested Decision is unclear because it does not define the term '*individual polymer*'. This argument must be rejected. It is clear from its wording that this term refers to each polymer manufactured from nonylphenol.

136. Second, according to the Appellants, the Contested Decision is unclear because it fails to specify if the information requirements apply only to polymers that fall within the definition of a '*substance*' for the purposes of the REACH Regulation. This argument must be rejected. It is clear that a polymer is a substance for the purposes of the REACH Regulation, and the term '*polymer*' is defined in Article 3(5).

137. Third, according to the Appellants, the Contested Decision is imprecise because it fails to specify whether the information requirements also apply to polymers in articles. This argument must be rejected. The purpose of information requests 2 to 6 is to clarify how nonylphenol is released into the environment. It is consequently clear that the information requirements must apply to any polymers made from nonylphenol manufactured or imported by the addressees of the Contested Decision whether or not these polymers are in articles.

138. Fourth, according to the Appellants, the Contested Decision is imprecise because it allows individual polymers to be '*grouped*' but does not indicate what method of '*grouping*' will be accepted. This argument must also be rejected. It is clear from the way in which this word is used in the Contested Decision, and was further clarified by HSE in its statement in intervention, that '*grouping*' in this context simply means the presentation of information for a number of polymers together (for example, by '*broad polymer types*').

139. Fifth, according to the Appellants, the Contested Decision is imprecise because it does not define the term '*annual supply tonnage*'. This argument must also be rejected. It is clear from the wording of the Contested Decision, and was further clarified by HSE through examples set out in the statement in intervention, that '*annual supply tonnage*' means the quantity supplied annually, expressed in whole tonnes. The *de minimis* limit for providing the information is therefore one tonne per year.

140. Sixth, with specific regard to information requirement 6 (update of all exposure scenarios to include the waste phase or justification as to why it is not relevant), the Appellants claim that they may not be able to provide the required information and it is unclear what the consequences of this would be. This argument must be rejected because the Appellants have not substantiated why they would not be able to provide the required information.

141. Seventh, according to the Appellants, it is uncertain how the information is to be submitted to the Agency. This argument must be rejected. It is clear, and was confirmed by the Agency in the hearing, that the Appellants can submit this information by email, mail or dossier update. The information can be submitted in one common document by all or several registrants or per registrant if they wish to submit the information individually.

142. Eighth, according to the Appellants, it is not clear whether information requirement 5 ('*Justification as to why registration dossiers do not include ES15 [Service life of paints containing NPEO] as a relevant use*') applies to all Appellants or only to those who have paint formulation as an exposure scenario. This argument must be rejected. It is clear that information requirement 5 can only apply to those Appellants who have paint formulation as an exposure scenario.

143. The Appellants' arguments that information requirements 2 to 6 breach the principle of legal certainty as regards information on the polymers that the Appellants manufacture or import themselves must consequently be rejected.

2.2.2.4. Conclusion

144. The Appellants' pleas and arguments are rejected insofar as they are directed against the obligation, set out in information requirements 2 to 6, to submit to the Agency information on nonylphenol and on polymers made from nonylphenol that the Appellants manufacture or import themselves.

2.3. Part D of Section II of the Contested Decision, requesting '*Information for environmental PNECs*' (information requirements 10 to 15)

145. Information requirements 10 to 15, set out in Part D of Section II of the Contested Decision (see paragraph 16 above), require the Appellants to:

- determine the no-observed-effects concentration ('NOEC') of nonylphenol for rainbow trout (information requirement 10) and winter flounder (information requirement 11) based on existing studies,
- perform long-term toxicity tests on aquatic molluscs (in *Potamopyrgus antipodarum* and *Crassostrea gigas*) and echinoderms (in a species to be chosen by the Appellants), unless '*a reliable chronic NOEC/EC 10 for reproduction and growth for these species [can] be derived from published studies in the literature*' (information requirements 12 and 13),
- revise the predicted no-effect concentration ('PNEC') of nonylphenol in marine and fresh surface waters (information requirement 14), and

- assess all available information on the avian toxicity of nonylphenol and provide observations on whether any further testing may be needed (information requirement 15).

146. The Appellants raise the following pleas in law against information requirements 10 to 15:

- a breach of the principle of proportionality,
- an '*unlawful act*' and an error of assessment,
- a breach of the duty to state reasons, and
- a breach of the animal welfare requirements in the REACH Regulation.

147. In addition, in the Notice of Appeal the Appellants also claimed that information requirements 10 to 15 breach the principles of legal certainty, '*legal expectation*', the protection of legitimate expectations, and good administration. In the hearing, however, the Appellants withdrew these pleas. They will therefore not be examined.

2.3.1. The pleas alleging breaches of the principle of proportionality, an '*unlawful act*' and an error of assessment

Arguments of the Appellants

148. The Appellants argue that nonylphenol is already so highly regulated, and the PNEC stated in the Appellants' registration dossiers (0.000613814 mg/l) is already so low, that the re-calculation of the PNEC, even based on the new information requested by the Contested Decision, would not lead to improved risk management measures. The Appellants applied an assessment factor of 5, which is the highest assessment factor foreseen in the Agency's Guidance on Registration (Chapter R.10, May 2008) for the species sensitivity distribution ('SSD') model used.

149. The Appellants further argue that, according to the minutes of the MSC meeting at which nonylphenol was discussed, the information requests at issue were maintained because they are '*potentially relevant to future authorisation applications for [NPEO]*'. However, information necessary for an application for authorisation of a use of NPEO should be provided by the persons applying for the authorisation and not by the registrants of nonylphenol.

150. Moreover, according to the Appellants, the information requests for long-term toxicity tests on rainbow trout, winter flounder, aquatic molluscs and echinoderms are not appropriate to achieve their objective because the results of those tests would not be '*reliable and useful*'. In particular, there are no standardised testing guidelines for assessing multi-generational effects in rainbow trout, reproduction effects in the mollusc *Potamopyrgus antipodarum*, or long term and transgenerational effects in the mollusc *Crassostrea gigas*.

151. The Appellants also argue that the information requests for testing on rainbow trout, winter flounder, aquatic molluscs and echinoderms are not the least onerous option. A prior literature review followed by a read-across from data on another substance (octylphenol) should be used instead.

152. Finally, the minutes of the meeting of the Member State Committee at which nonylphenol was discussed state that '*[HSE] decided not to drop [sic] the information requests related to data that affect the aquatic PNEC, since [it] considered these [data] potentially relevant to future authorisation applications for [NPEO]*'. According to the Appellants, this constitutes an error of assessment and an '*unlawful act*' because, at the time, NPEO had not been included in Annex XIV.

Arguments of the Agency and the Intervener

153. The Agency, supported by the Intervener, points out that the Contested Decision does not require testing on vertebrate animals, but only on aquatic molluscs and echinoderms. For the remaining information requests the Contested Decision requires the Appellants to perform an analysis of data that already exist.

154. According to the Agency, the purpose of the information requests in Part D of Section II of the Contested Decision is to determine whether the PNEC identified by the Appellants is correct, i.e. if it is sufficiently '*protective*' of the environment.

155. Certain species may be more sensitive to nonylphenol than the Appellants assume. The Registrants are therefore requested to review their choice of studies and endpoints used for determining the species sensitivity distribution and to carry out two further tests on invertebrates to support the analysis.

156. The Agency argues that further information could lower the PNEC considerably. '*This is because the data could affect the tail of the distribution (which influences the HC5 value [the hazardous concentration affecting 5% of species] derived), as well as the resulting consistency with the assumption of normality and therefore the statistics used to derive the HC5.*'

157. In the environmental exposure assessments included in the Appellants' registration dossiers the risk characterisation ratio in several scenarios is close to 1. A small change in PNEC could cause the ratio to exceed 1 and therefore require the Appellants to implement additional risk management measures. It is therefore necessary for the Appellants to ensure that the PNEC used is reliable and sufficiently protective.

158. Moreover, the reliability of the PNEC for nonylphenol is directly relevant to the authorisation of other substances, such as NPEO, which are included in Annex XIV and have nonylphenol as a degradation product.

159. Finally, as regards the studies on aquatic molluscs and echinoderms, according to the Agency, the Contested Decision indicates the test methods to be used. Under Article 13(4), the Agency may require tests to be carried out that it considers to be appropriate. It is not bound to impose only those test methods that have been formally adopted by the Organisation for Economic Co-operation and Development ('OECD').

Findings of the Board of Appeal

160. The principle of proportionality requires that a measure should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question. Where 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 9 June 2016, *Pesce and Others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 48; see also Case A-023-2015, *Akzo Nobel and Others*, Decision of the Board of Appeal of 13 December 2017, paragraph 293).

161. The Board of Appeal will examine the Appellants' arguments in the following order:
    - whether further information is necessary to establish the PNEC (Section 2.3.1.1.),
    - whether information requirements 10 to 15 are appropriate to achieve the objective pursued (Section 2.3.1.2.),
    - whether information requirements 10 to 15 are the least onerous of several appropriate measures (Section 2.3.1.3.), and
    - whether the Agency committed an '*unlawful act*' or an error of assessment (Section 2.3.1.4.).

2.3.1.1. Whether further information is necessary to establish the PNEC

162. The objective of information requirements 10 to 15 is to obtain information on the effects of nonylphenol on a greater number of species than are currently included in the SSD model, thereby making the PNEC more realistic, precise and reliable.

163. An assessment of the risk posed by a chemical is based on risk characterisation ratios ('RCRs'). RCRs are derived by comparing exposure levels to relevant predicted no-effect concentrations (PNECs) or derived no-effect levels (DNELs).

164. In this case, the PNEC is calculated on the basis of an SSD model.

165. The organisms included in the SSD model, the types of endpoint and life stages tested, the way in which data are combined for individual species, and the assessment factor applied to take account of uncertainties, are all highly relevant aspects for the calculation of the PNEC.

166. For example, if a specific taxonomic group is particularly sensitive to a substance, an SSD model that includes data for a wide range of less sensitive taxonomic groups may not lead to the calculation of the correct PNEC, thereby leading to an under-estimation of the RCR.

167. In the present case, the SSD model for nonylphenol has been established on the basis of a number of taxonomic groups, leading to a PNEC of 0.6 µg/l in freshwater. However, as stated in the Contested Decision, and not contested by the Appellant, there are several studies which suggest that the margin of safety this provides for some taxonomic groups is low, and may be insufficient in some cases.

168. Data on further taxonomic groups, as requested under information requirements 10 to 15, is therefore necessary to ensure that the PNEC for nonylphenol is sufficiently protective of the environment.

169. This information will allow the SSD model to be confirmed or recalibrated, as the case may be, and, consequently, the PNEC and the RCR to be confirmed or re-calculated. Greater confidence in the PNEC and RCR will ensure that the risk management measures in place, to keep the RCR below 1, are appropriate to the risks posed.

170. Finally, it is irrelevant whether or not the Agency's Guidance on Registration lists an assessment factor of 5 at most, as the Appellants argue. Information requirements 10 to 15 aim to ensure that the PNEC, and therefore the RCR, is as realistic, precise and reliable as possible. This is entirely consistent with the objectives of substance evaluation.

171. The Appellants' arguments that information requirements 10 to 15 are not necessary must consequently be rejected.

2.3.1.2. Whether information requirements 10 to 15 are appropriate to achieve the objective pursued

172. The Appellants argue that the information requests for long-term toxicity tests on rainbow trout, winter flounder, aquatic molluscs and echinoderms are not appropriate to achieve their objective because the results of those tests would not be '*reliable and useful*'. In particular, according to the Appellants, there are no standardised testing guidelines for assessing multi-generational effects in rainbow trout, reproduction effects in the mollusc *Potamopyrgus antipodarum*, or long term and transgenerational effects in the mollusc *Crassostrea gigas*.

173. However, the Appellants misread the Contested Decision. It does not require testing on rainbow trout or winter flounder. The Appellants' argument must therefore be rejected as inoperative in this regard.

174. It must further be noted that, in accordance with Article 46, the Agency may require a test to be carried out through any suitable methodology. The absence of officially adopted OECD test guidelines does not in itself mean that the results of a test will not contribute to the clarification of the concern identified. Test methods that have not (yet) been officially adopted or agreed may still be able to clarify a hazard. For example, a test method may address such a niche effect that it has not been considered for adoption by the OECD. This does not mean however that the test is not relevant to the assessment of that hazard. The Appellants' arguments based on the absence of officially adopted test guidelines must consequently be rejected as unfounded.

2.3.1.3. Whether information requirements 10 to 15 are the least onerous of several appropriate measures

175. The Appellants argue that information requirements 10 to 15 are not the least onerous option available to the Agency. A prior literature review followed by a read-across from data on another substance (octylphenol) should be used instead.

176. This argument must be rejected for the following reasons.

177. First, the Appellants overestimate the burden of testing. They mistakenly assume that the Contested Decision requires testing on rainbow trout and winter flounder. It does not.

178. Second, the Appellants refer to '*a read-across of data from octylphenol*', but fail to substantiate this argument and the basis for the read-across in these appeal proceedings. In particular, the Appellants have not attempted to establish that data can be read across from octylphenol to nonylphenol, and they have not indicated to which data they would wish to apply a read-across approach.

179. Third, the '*stepwise approach*' put forward by the Appellants is not a suitable alternative to the information requests. The Appellants have not established that a literature review would add any information to that which has already been assessed.

2.3.1.4. '*Unlawful act*' and error of assessment

180. The minutes of the meeting of the Member State Committee at which nonylphenol was discussed state that '*[HSE] decided not to drop [sic] the information requests related to data that affect the aquatic PNEC, since [it] considered these [data] potentially relevant to future authorisation applications for [NPEO]*'. According to the Appellants, this constitutes an error of assessment and an '*unlawful act*' because, at the time, NPEO had not yet been included in Annex XIV.

181. The Agency has established that further information is necessary in order to clarify a potential concern posed by nonylphenol (see Section 2.3.1.1. above). As this is in itself a sufficient ground for requiring the information at issue, the Appellants' argument concerning the additional ground mentioned in the minutes of the MSC meeting is inoperative.

2.3.1.5. Conclusion

182. For the reasons stated above, the Appellants' pleas alleging breaches of the principle of proportionality, an '*unlawful act*', and an error of assessment, must be rejected.

2.3.2. The plea alleging a breach of the duty to state reasons

Arguments of the Parties

183. The Appellants argue that the Agency breached its duty to state reasons by failing to explain why information requests 10 to 15 are proportionate.

184. The Agency argues that the Contested Decision is adequately reasoned.

Findings of the Board of Appeal

185. The Appellants confuse the requirements of the duty to state reasons, which is a matter of form, with the issue of the correctness of those reasons, which is a matter of substance (see, to this effect, judgment of 16 November 2017, *Ludwig-Bölkow-Systemtechnik* v *Commission*, EU:C:2017:871, paragraph 16; see also Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 128).

186. The Contested Decision sets out the reasons for requesting the information at issue in Section III. The Board of Appeal has already examined the Appellants' arguments concerning the substantive correctness of those reasons in Section 2.3.1. above.

187. The Appellants' plea that the Agency breached the duty to state reasons by failing to explain why information requests 10 to 15 are proportionate must therefore be rejected.

2.3.3. The plea alleging a breach of animal welfare requirements

Arguments of the Appellants

188. The Appellants argue that the Agency breached the animal welfare provisions in the REACH Regulation. In particular:

- the Contested Decision requires unjustified testing on vertebrate animals, and
- in the statement of reasons of the Contested Decision, the Agency invited the registrants to provide observations on whether avian testing could be necessary, stating that '*the possible need for further testing will be considered by the evaluating MSCA in the follow up evaluation*'. The Appellants argue that this might constitute '*legal authority*' for the Agency to request animal testing at a later stage without '*further legal scrutiny*'.

Arguments of the Agency

189. According to the Agency, the Contested Decision does not require testing on vertebrate animals.

Findings of the Board of Appeal

190. The Appellants' arguments concerning vertebrate animal testing are based on a series of misunderstandings or misrepresentations of the Contested Decision.

191. The Contested Decision does not require any testing on vertebrate animals. It rather requires the assessment of results from existing tests, and testing on invertebrate animals.

192. Moreover, Article 46(3) sets out the follow-up procedures once information has been submitted consequent to a substance evaluation decision. Under this provision, any testing on vertebrate animals can only be required if the decision-making procedures set out in Articles 50 and 52 have been followed. Any request for further animal testing must therefore undergo further legal scrutiny.

193. The Appellants' plea that information requirements 10 to 15 breach the animal welfare requirements of the REACH Regulation must therefore be rejected.

2.4. The deadline given in the Contested Decision

Arguments of the Appellants

194. The Appellants argue that the deadline for providing the information required by the Contested Decision, namely one year, six months and eight days, is disproportionate because it is too short.

195. According to the Appellants, obtaining the information required by Part B of Section II of the Contested Decision (information requirements 2 to 6) will be time-consuming because it will require information to be obtained from complex supply chains.

196. In the Notice of Appeal, the Appellants also raised arguments on the deadline as regards Part D of Section II of the Contested Decision (information requirements 10 to 15). However, the Appellants withdrew these arguments in the hearing. They will therefore not be examined.

Arguments of the Agency

197. The Agency argues that the deadline set in the Contested Decision affords the Appellants sufficient time to comply with the information requests.

Findings of the Board of Appeal

198. The Appellants' claim that the deadline given in the Contested Decision is too short was based on the difficulty of obtaining the information required under Part B of Section II of the Contested Decision from downstream users or in making '*reasonable worst case assumptions*'.

199. As the obligation to obtain information from downstream users and to make calculations using '*reasonable worst case assumptions*' is annulled on other grounds (see paragraphs 114 and 115 above), there is no need to examine this argument.

Claim for reimbursement of costs

200. The Appellants request the reimbursement of the costs incurred for these proceedings.

201. In accordance with Article 17a of Commission Regulation (EC) No 771/2001 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), the parties to an appeal bear their own costs.

202. In footnote 46 to Annex 1 to their reply to questions from the Board of Appeal (see paragraph 24 above), the Appellants claim that this provision is unlawful. By this argument, the Appellants effectively raise an incidental plea of illegality against the Rules of Procedure. However, the Board of Appeal is not competent to decide on the legality of the Rules of Procedure, which is a Commission implementing regulation (see Case A-004-2011, *Kronochem*, Decision of the Board of Appeal of 7 October 2011, paragraph 66). The Appellants' arguments to this effect are therefore inadmissible.

203. The application for the reimbursement of costs is therefore rejected.

Refund of the appeal fee

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

205. In the circumstances of the present case, the greater and most burdensome part of the contested information requirements has been annulled. The appeal fee must therefore be refunded.

Effects of the Contested Decision

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

207. The Contested Decision required the Appellants to provide the information at issue by 6 November 2017, which is one year, six months and eight days from the date of its notification.

208. The Appellants must therefore provide the information required by Parts B and D of the Contested Decision, insofar as they are not annulled, by 14 December 2019.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. Annuls Part B of Section II of the Contested Decision insofar as it requires the Appellants to submit information on polymers that they do not themselves manufacture or import or, alternatively, make '*reasonable worst case assumptions*' regarding those polymers, and remits the case to the competent body of the Agency for further action in this regard.

2. **Dismisses the appeal as regards Part B of Section II of the Contested Decision insofar as it requires the Appellants to submit the following information:**
   - **The annual tonnage of the registered substance manufactured and placed on the market by each registrant for each of the exposure scenarios in the Chemical Safety Report.**
   - **The annual supply tonnage of individual polymers (e.g. resins, NPEO, etc.) (which can be grouped if justified) that are manufactured or imported by the registrants, broken down by use (estimated if necessary). This information can be provided separately by each registrant if it is commercially sensitive.**
   - **Information on the typical concentration of the registered substance as an unreacted impurity in polymers manufactured or imported by the registrants and the potential for its formation from these polymers during environmental degradation. This information can be provided separately by each registrant if it is commercially sensitive. Following an assessment of relevance, exposure scenarios shall be produced for significant sources.**
   - **Justification as to why exposure scenarios involving NPEO do not take account of the further degradation of NPEO released in waste water treatment plant effluent to the registered substance.**
   - **Justification as to why registration dossiers do not include ES15 (service life of paints containing NPEO) as a relevant use when they include ES9 (formulation of paints containing NPEO).**
   - **An update of all exposure scenarios to include the waste phase or justification as to why it is not relevant. This should include all lifecycle steps, including production/formulation/processing and disposal of products containing the registered substance at the end of their service life, or containing polymers insofar as the relevant information is available to the registrants.**
3. **Dismisses the appeal as regards Part D of Section II of the Contested Decision.**
4. **Decides that the information required by Parts B and D of Section II of the Contested Decision, insofar as they are not annulled, must be submitted by 14 December 2019.**
5. **Decides that the appeal fee must be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal