Reports of Cases

OPINION OF ADVOCATE GENERAL
TANCHEV
delivered on 29 October 2020[1]

Case C-389/19 P

European Commission
v

Kingdom of Sweden

(Appeal – Regulation (EC) No 1907/2006 (REACH Regulation) – Articles 56, 58 and 60 – Authorisation – Substances of very high concern – Commission Decision authorising the use of lead sulfochromate yellow and lead chromate molybdate sulfate red – Assessment of the lack of suitable alternatives – Action for annulment – Maintenance of effects)

I. Introduction

1. In this appeal, the European Commission requests the Court of Justice to set aside the judgment of 7 March 2019, *Sweden* v *Commission* (T-837/16, EU:T:2019:144; 'the judgment under appeal'), by which the General Court annulled Commission Implementing Decision C(2016) 5644 final of 7 September 2016 granting an authorisation for some uses of lead sulfochromate yellow and of lead chromate molybdate sulfate red under Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('the decision at issue') and rejected the Commission's request to maintain the effects of that decision until it was replaced by a new decision.

2. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[2] ('the REACH Regulation') establishes an authorisation regime for substances of very high concern as regards their risks to human health and the environment. Generally, under that regime, once such a substance is included in Annex XIV to that regulation, it cannot be used or placed on the market after a certain date unless a specific authorisation is granted by the Commission.

1 Original language: English.

2 OJ 2006 L 396, p. 1.

3. Consequently, the present case provides the Court with the opportunity to rule for the first time on the conditions under which the Commission may grant an authorisation, on the basis of Article 60 of the REACH Regulation, for a substance of very high concern listed in Annex XIV to that regulation.[3] The key issue raised by this case concerns the assessment carried out by the Commission regarding the lack of suitable alternatives, which is one of the main requirements for an authorisation to be granted under Article 60(4) of the REACH Regulation. Should the Court uphold the annulment of the decision at issue, this case also raises the novel question whether its effects should be maintained until the Commission takes a new decision, having regard to the transitional rules in Articles 56 and 58 of the REACH Regulation.

II. Legal framework

4. Title VII of the REACH Regulation, entitled 'Authorisation', devotes Chapter 1 to 'Authorisation requirement' and Chapter 2 to 'Granting of authorisations'. Chapter 1 includes in particular Articles 56 and 58. Chapter 2 contains in particular Article 60.

5. Article 56 of the REACH Regulation, entitled 'General provisions', states:

'1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:

(a) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or

…

(d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; …

…'

6. Article 58 of the REACH Regulation, entitled 'Inclusion of substances in Annex XIV', provides:

'1. Whenever a decision is taken to include in Annex XIV substances referred to in Article 57, such a decision shall be taken in accordance with the procedure referred to in Article 133(4). It shall specify for each substance:

…

(c) transitional arrangements:

(i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) which should take into account, where appropriate, the production cycle specified for that use;

3 There is another case pending before the Court which raises similar, though not identical, issues relating in particular to the Commission's assessment of alternatives in the context of its rejection of a request for internal review of an authorisation decision: see *ClientEarth* v *Commission*, C-458/19 P (see further points 92 and 93 of this Opinion). A case involving the Commission's rejection of a request for internal review of the decision at issue is also pending before the General Court: see *ClientEarth and Others* v *Commission*, T-436/17.

(ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;

…'

7. Article 60 of the REACH Regulation, entitled 'Granting of authorisations', provides in paragraphs 4 and 5 thereof:

'4. If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account the opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis referred to in Article 64(4)(a) and (b):

(a) the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;

(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;

(c) the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);

(d) available information on the risks to human health or the environment of any alternative substances or technologies.

5. When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:

(a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;

(b) the technical and economic feasibility of alternatives for the applicant.'

III. Background to the proceedings

8. The background to the proceedings, as set out in paragraphs 1 to 30 of the judgment under appeal, can be summarised as follows for the purposes of the present case. It is necessary to provide some preliminary observations on the REACH Regulation and the authorisation regime (section A), before turning to the events leading to the proceedings before the General Court (section B).

A. The REACH Regulation and the authorisation regime

9. The REACH Regulation is a key legal instrument governing the regulation of chemicals in the EU. As the Court has recognised, under Article 1(1) of that regulation, its purpose 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. [4]

10. In particular, as is made clear, inter alia, in recitals 69 and 70 of the REACH Regulation, that regulation makes substances of very high concern subject to careful attention. Those substances are thus subject to the authorisation regime laid down in Title VII of the REACH Regulation. Article 55 of that regulation states that the aim of that regime is 'to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable'. [5]

11. The authorisation regime comprises three stages. [6] The first stage is the procedure for identifying substances of very high concern on the basis of the criteria set out in Article 57 of the REACH Regulation. The second stage is the inclusion of those substances on the list of substances subject to authorisation in Annex XIV to that regulation. The third stage – in which the present case is situated – concerns the procedure that leads, if appropriate, to the granting of an authorisation for a substance of very high concern. [7]

12. In consequence, as set out in Articles 56 and 58 of the REACH Regulation, substances of very high concern included in Annex XIV to that regulation cannot be used or placed on the market for a use by manufacturers, importers or downstream users after a specified date ('the sunset date'), unless the use has been authorised or certain limitations apply, including where an application for authorisation was submitted before the latest application date indicated for the substance, but a decision has not yet been taken by the Commission. [8]

13. Manufacturers and importers can submit applications for authorisation to place a substance on the market, to use that substance themselves and to grant its use to their downstream users. [9] While those applications are made to the European Chemicals Agency ('ECHA'), [10] established by that regulation to help administer its provisions, it is the Commission that takes the decision. [11] Authorisation decisions specify, inter alia, the use(s) covered, the time period for review of the authorisation and the conditions to which the authorisation is subject. [12]

14. Importantly, Article 60 of the REACH Regulation establishes two possible routes by which an authorisation can be granted by the Commission: first, the adequate control route under Article 60(2) of the REACH Regulation, where the risk from using the substance is adequately controlled, and, second, the socio-economic route under Article 60(4) of the REACH Regulation, at issue here, which requires the fulfilment of two cumulative criteria, namely (i) that the socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and (ii) that there are no suitable alternative substances or technologies. [13]

4 See, for example, judgment of 15 March 2017, *Polynt* v *ECHA* (C-323/15 P, EU:C:2017:207, paragraph 20).

5 See, for example, judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802, paragraph 55).

6 For a detailed discussion, see, for example, Herbatschek, N. et al., 'The REACH Programmes and Procedures', in Bergkamp, L. (ed.), *The European Union REACH Regulation for Chemicals: Law and Practice*, Oxford University Press, 2013, pp. 83-170, at pp. 133-146.

7 See, for example, judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802, paragraph 56).

8 See the REACH Regulation, Articles 56(1)(a) and (d) and 58(1)(c)(ii).

9 See the REACH Regulation, Articles 56(1)(e) and (2) and 62(2) and (3).

10 See the REACH Regulation, Article 62(1).

11 See the REACH Regulation, Article 60(1).

12 See the REACH Regulation, Articles 60(8) and (9) and 61; recital 72.

13 See also the REACH Regulation, recitals 22 and 69.

15. Article 60(4) of the REACH Regulation instructs the Commission to take the decision after consideration of several elements, including in particular the analysis of the alternatives submitted by the applicant [14] and any third party submissions as part of the procedure, along with the opinions of the Committees for Risk Assessment and for Socio-economic Analysis. Article 60(5) of the REACH Regulation further stipulates that, when assessing whether suitable alternatives are available, the Commission must take account of all relevant aspects, including, first, whether the transfer to alternatives would result in reduced overall risks to human health and the environment and, second, the technical and economic feasibility of alternatives for the applicant.

16. In that connection, the Commission takes the decision following the procedure set out in Article 64 of the REACH Regulation. In particular, this involves, pursuant to Article 64(2) of that regulation, a public consultation, which gives third parties the opportunity to submit information on alternative substances or technologies. Under Article 64(3) and (4) of the REACH Regulation, the Committees for Risk Assessment ('the RAC') and for Socio-economic Analysis ('the SEAC'), which are entities within ECHA to carry out various tasks, [15] must give their opinions on relevant aspects of the application, which in the case of the SEAC include the availability of alternatives. Under Article 64(8) of the REACH Regulation, the Commission prepares a draft decision within three months of receipt of those opinions and adopts the final decision in accordance with the applicable comitology procedure. [16]

B. Events leading to the proceedings before the General Court

17. Lead sulfochromate yellow (C.I. Pigment Yellow 34) and lead chromate molybdate sulfate red (C.I. Pigment Red 104) (together, 'the substances at issue') are substances composed of lead and chromium VI. Due to their durability, light colour and brightness, they have been used in particular in varnishes and paints (for example, for iron and steel bridges and constructions), to fulfil a signalling function (such as on warning signs) and for yellow road markings.

18. By virtue of Regulation No 125/2012, [17] the substances at issue were included on the list of substances of very high concern in Annex XIV to the REACH Regulation on account of their properties as carcinogens and human reproductive toxicants. As a result, their use and placement on the market was subject to authorisation after 21 May 2015 (the sunset date) and the latest application date was 21 November 2013.

19. On 19 November 2013, DCC Maastricht BV ('DCC Maastricht' or 'the applicant'), [18] which supplies the substances at issue to approximately 100 downstream users in the EU, submitted an application for authorisation ('the application for authorisation') to place those substances on the market for the following six uses, which are identical for both substances:

– distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use ('use 1');

– industrial application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, coil coating, etc.) ('use 2');

14 Under Article 62(4)(e) of the REACH Regulation, an application for authorisation must include, inter alia, an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution.

15 See, in particular, the REACH Regulation, Articles 76(1)(c) and (d), 77(3) and 85.

16 See also the REACH Regulation, recital 83.

17 See Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV to Regulation No 1907/2006 (OJ 2012 L 41, p. 1), recitals 6 and 7; Annex, Entry Numbers 11 and 12.

18 As indicated by paragraph 5 of the judgment under appeal, DCC Maastricht is the only representative, within the meaning of Article 8 of the REACH Regulation, of a non-EU (Canadian) manufacturer of the substances at issue, such that it represents it for the purposes of registering its substances under that regulation.

– professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, etc.) or as road marking ('use 3');

– distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use ('use 4');

– industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use ('use 5'); and

– professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking ('use 6').

20. In the public consultation, held in accordance with Article 64(2) of the REACH Regulation, manufacturers, downstream users of the substances at issue, industry organisations, Member States and non-governmental organisations submitted opinions on the application for authorisation. In particular, those downstream users stated that possible alternative substances did not offer the same advantages and were more expensive in most cases. In contrast, members of the paint and coatings industry indicated that there were safer and suitable alternative substances that could be used at reasonable cost. DCC Maastricht responded that a number of undertakings needed the substances at issue to manufacture specific products intended for certain 'niche' uses.

21. On 11 December 2014, the RAC and the SEAC adopted 12 consolidated opinions on each of the six uses for the two substances at issue. In its opinions, the SEAC 'confirmed that there appear *not* to be suitable alternatives in terms of their technical and economic feasibility for the applicant'.

22. At meetings held on 7 and 8 July 2015, 22 and 23 September 2015, 3 and 4 February 2016 and 6 and 7 July 2016, the application for authorisation was examined within the comitology committee set up under Article 133 of the REACH Regulation ('the REACH Committee'). In particular, two Member States and the Kingdom of Norway indicated that the substances at issue were not used for yellow road markings, and in one of those Member States, such use was prohibited 20 years ago. The REACH Committee ultimately delivered a positive opinion on the Commission's draft decision; 23 Member States voted in favour, whilst 3 Member States, including the Kingdom of Sweden, voted against and 2 Member States abstained.

23. On 7 September 2016, the Commission adopted the decision at issue. By that decision, it granted an authorisation to DCC Maastricht, on the basis of Article 60(4) of the REACH Regulation, for the substances at issue as regards the six uses applied for, subject to certain conditions and limitations ('the authorisation').

24. In recitals 8 and 9 of the decision at issue, the Commission stated that, given 'the difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope of those … uses', the authorisation should be reviewed earlier than recommended by the SEAC. It further noted in recital 9 of that decision that, after further verification with Member States, it appeared that the use of the substances at issue in the road marking sector was substituted or prohibited in some Member States, but not in others. Thus, according to the Commission, it was appropriate to set the review period at 7 years, instead of 12 years, for uses 1, 2, 4 and 5 and at 4 years, instead of 7 years, for uses 3 and 6.

25. In recital 12 of the decision at issue, the Commission stated:

'Due to the difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope of the uses covered by the application, it is appropriate to further specify the authorised uses, in terms of the technically required performance characteristics of pigment premixes, paints and pre-compounds and of articles containing them, imparted by the two substances that cannot be

achieved by any other suitable alternative substance or technology. The authorisation should therefore be subject to the condition that the authorisation holder submits a report on the status of the suitability and availability of alternatives for his downstream users and on that basis refines the description of the authorised uses. …'

26. In Article 1(1) and (2) of the decision at issue, the Commission authorised the six uses of the substances at issue applied for 'under the condition that the performance of the pigment premixes, paints and colour pre-compounds containing [the substances at issue], or of finished articles containing them, in terms of shade functionality and chroma, opacity (hiding power), dispersibility, durability (light and weather fastness), heat stability or non-leaching behaviour, or a combination thereof, is technically achievable only by using that substance and that such performance is necessary for the intended use'.

27. In Article 1(3)(d) of the decision at issue, the authorisation is subject to the condition that the authorisation holder's downstream users must submit to ECHA by 30 June 2017 information on the status of the suitability and availability of alternatives for their uses, providing a detailed justification of the need to use the substances at issue.

28. In Article 1(3)(e) of the decision at issue, the authorisation is subject to the condition that the authorisation holder must submit to the Commission by 31 December 2017 a report on the elements referred to in Article 1(3)(d) of that decision. The authorisation holder is required to refine, in that report, the description of the authorised uses, based on information on alternatives provided by its downstream users.

29. Finally, in Article 3(b) of the decision at issue, at the request of the relevant Member State competent authority, the downstream users must substantiate why the conditions of Article 1(1) and (2) apply and why the performance parameters are necessary for the intended use.

IV. The proceedings before the General Court and the judgment under appeal

30. On 28 November 2016, the Kingdom of Sweden brought an action to annul the decision at issue before the General Court.

31. The Commission claimed that the action should be dismissed. It also requested the General Court, if the decision at issue was annulled, to maintain its effects until it was replaced by a new decision.

32. By decisions of 24 March and 3 May 2017, the President of the Fifth Chamber of the General Court granted the Kingdom of Denmark, the Republic of Finland and the European Parliament leave to intervene in support of the form of order sought by the Kingdom of Sweden. In addition, by order of 20 July 2017, ECHA was granted leave to intervene in support of the form of order sought by the Commission.

33. By the judgment under appeal, the General Court upheld the second part of the first plea raised by the Kingdom of Sweden, alleging that the Commission infringed Article 60(4) of the REACH Regulation by granting the authorisation without having duly established that there were no suitable alternatives to replace the substances at issue for the uses applied for, and annulled the decision at issue (paragraphs 57 to 106 of the judgment under appeal).[19]

34. The General Court also rejected the Commission's request to maintain the effects of the decision at issue until it was replaced by a new decision (paragraphs 107 to 112 of the judgment under appeal).

19 The General Court found it unnecessary to examine the other arguments and pleas raised in the case (paragraphs 46, 47 and 106 of the judgment under appeal).

V. The proceedings before the Court of Justice and the forms of order sought

35. By the present appeal, lodged on 20 May 2019, the Commission requests that the Court set aside the judgment under appeal, dismiss the action brought by the Kingdom of Sweden and order the Kingdom of Sweden to pay the costs. In the alternative, the Commission requests that the Court refer the case back to the General Court for reconsideration, reserve the costs at first instance and on appeal, and maintain the effects of the decision at issue.

36. ECHA, which intervened at first instance in support of the Commission, supports the form of order sought by the Commission.

37. The Kingdom of Sweden requests that the Court dismiss the appeal and order the Commission to pay the costs.

38. The Kingdom of Denmark, the Republic of Finland and the Parliament, interveners at first instance in support of the Kingdom of Sweden, support the form of order sought by the Kingdom of Sweden.

39. By order of 21 November 2019,[20] the Vice-President of the Court granted the Commission's request for interim measures to suspend the operation of the judgment under appeal pending the outcome of the appeal against that judgment.

40. A hearing was held on 7 July 2020 at which the Kingdom of Denmark, the Kingdom of Sweden, the Parliament, the Commission and ECHA presented oral argument.

VI. Analysis

41. The Commission raises four grounds of appeal. The first ground is based on the incorrect assessment of the standard of proof concerning the lack of suitable alternatives under Article 60(4) of the REACH Regulation. The second ground is based on the failure to consider the Commission's discretionary powers to set a zero threshold for technical feasibility of alternatives pursuant to Article 60(4) of the REACH Regulation. The third ground is based on the misapplication of Article 60(4) of the REACH Regulation as regards the partial scope and conditions of authorisation in the decision at issue. The fourth ground is based on the incorrect assessment of the request to maintain the effects of the decision at issue.

42. For the reasons set out below, I consider that the first, second and third grounds of appeal are unfounded, while the fourth ground is well founded. In those circumstances, I take the view that point 2 of the operative part of the judgment under appeal should be set aside and the Court should maintain the effects of the decision at issue until it is replaced by a new decision.

A. First ground of appeal (relating to the standard of proof applicable to the lack of suitable alternatives)

1. Summary of the arguments of the parties

43. By the first ground of appeal, the Commission, supported generally by ECHA, contends, in essence, that the General Court committed a manifest error of law, in paragraphs 79, 81, 85, 86, 90 and 101 of the judgment under appeal, as regards the standard of proof applicable to the lack of suitable alternatives under Article 60(4) of the REACH Regulation.

20 *Commission* v *Sweden* (C-389/19 P-R, not published, EU:C:2019:1007). See further footnote 35 of this Opinion and accompanying text.

44. First, the Commission claims that the General Court imposed an impossible standard of proof by requiring the applicant for authorisation and the Commission to eliminate all scientific uncertainty in order to prove there are no suitable alternatives under Article 60(4) of the REACH Regulation. In its view, the evaluation of alternatives involves a scientific assessment which is characterised by substantial uncertainty, with the result that if all such uncertainty must be excluded, this constitutes a '*probatio diabolica*' (that is, a legal requirement to provide proof which is impossible to obtain).

45. Second, the Commission criticises the General Court's finding that, on the date of adoption of the decision at issue, significant uncertainties remained as regards the lack of suitable alternatives. It claims that the weight of evidence, including uncertainties, showed that the alternatives did not achieve the same level of technical performance as the substances at issue. It was therefore entitled to conclude, on the basis of its application of a zero threshold for the loss of technical performance, that the alternatives were not technically feasible and hence unsuitable for the authorised uses.

46. In that regard, the Commission emphasised at the hearing that its argument concerning the application of a zero threshold for technical feasibility of alternatives is admissible, since it constitutes a question of law, relating to the Commission's assessment of alternatives under Article 60(4) of the REACH Regulation, and it is not a new argument, since it was advanced, inter alia, in its written pleadings before the General Court. It also asserts that its appeal against the General Court's findings makes it necessary to develop that argument in more detail.

47. The Kingdom of Sweden, supported by the Kingdom of Denmark and the Parliament, submits that the first ground of appeal is inadmissible. The Kingdom of Sweden argues that the Commission's application of a zero threshold for technical feasibility of alternatives is a new argument which was not raised before the General Court and thus cannot be considered by the Court of Justice on appeal. For the Kingdom of Denmark and the Parliament, this ground relates to the General Court's factual assessments, which cannot be reviewed by the Court of Justice in the context of appeal proceedings.

48. The Kingdom of Sweden, supported by the Kingdom of Denmark, the Republic of Finland and the Parliament, further contends that the first ground of appeal is unfounded. They take the view that the General Court did not impose an impossible standard of proof regarding the assessment of the lack of suitable alternatives and that the Commission's allegations are based on a misreading of the judgment under appeal. The Kingdom of Sweden also disputes the Commission's application of a zero threshold for technical feasibility of alternatives, since it is not apparent from the decision at issue or other documents in the case file and it is not in conformity with Article 60(4) of the REACH Regulation. In particular, this is because it does not take into account that technical performance must be necessary to fulfil a specific function in the use for which authorisation is sought. It thus renders meaningless the requirement relating to the unavailability of alternatives, since no substance has exactly the same technical properties as another.

2. Assessment of the first ground of appeal

(a) Admissibility

49. First, the Kingdom of Denmark and the Parliament essentially challenge the admissibility of the first ground of appeal because it relates to the General Court's assessment of the facts and evidence on the basis of which it found that the Commission had not duly established the lack of suitable alternatives in accordance with Article 60(4) of the REACH Regulation. In the absence of allegations that the facts and evidence were distorted, that assessment cannot be reviewed by the Court of Justice in the context of appeal proceedings.

50. In my view, that plea of inadmissibility cannot succeed. The question whether the General Court erred as regards the standard of proof applicable to the lack of suitable alternatives under Article 60(4) of the REACH Regulation concerns whether the General Court has applied the correct legal standard as the basis for its appraisal of the facts and evidence, which is a question of law amenable to review by the Court of Justice on appeal.[21] In addition, the question whether the General Court could correctly conclude on the basis of the facts and evidence before it that the Commission erred in its assessment of the lack of suitable alternatives under Article 60(4) of the REACH Regulation concerns the legal characterisation of the facts of the case, which the Court of Justice has jurisdiction to review on appeal.[22]

51. Second, the Kingdom of Sweden challenges the admissibility of the first ground of appeal as regards the Commission's allegations concerning the application of a zero threshold for technical feasibility of alternatives on the ground that it is a new argument which was not raised before the General Court and thus cannot be considered by the Court of Justice on appeal.

52. In my view, that plea of inadmissibility also cannot succeed. Under settled case-law, an appellant is entitled to lodge an appeal relying on grounds which arise from the judgment under appeal itself and seek to criticise, in law, its correctness,[23] as is the case here. By its argument concerning the application of a zero threshold for technical feasibility of alternatives, the Commission seeks to demonstrate that for that reason there were no significant uncertainties regarding the lack of availability of alternatives and that it carried out a proper assessment of that requirement under Article 60(4) of the REACH Regulation. Accordingly, that argument is intended to challenge the correctness, in law, of the General Court's application of that provision in the judgment under appeal. Moreover, that argument had been raised by the Commission in its written submissions before the General Court with regard in particular to the second part of the Kingdom of Sweden's first plea in law, which was the basis for the General Court's annulment of the decision at issue.

53. Thus, I consider that the first ground of appeal is admissible.

(b) Substance

54. By the first ground of appeal, the Commission contends that the General Court erred in law in imposing an impossible standard of proof under Article 60(4) of the REACH Regulation, requiring the applicant for authorisation and the Commission to eliminate all substantial uncertainty that there are no suitable alternatives. In that respect, it claims that, based on its application of a zero threshold for technical feasibility of alternatives, there were no significant uncertainties in its evaluation of suitable alternatives at the time that the decision at issue was taken.

55. In my view, the first ground of appeal should be dismissed.

56. It seems to me that the Commission's reading of paragraphs 79, 81, 85, 86, 90 and 101 of the judgment under appeal is not convincing. Those paragraphs must be read in their proper context. Thus, the first ground of appeal appears to be based on a misreading of the judgment under appeal.

57. First, it is clear that, in paragraphs 79, 81, 85, 86, 90 and 101 of the judgment under appeal, when read together in particular with paragraphs 77, 78, 84 and 87 to 98 thereof, the General Court did not require that all scientific uncertainty be excluded on the part of the applicant for authorisation or the Commission. On the contrary, in those paragraphs, the General Court applied, in my view, a

21 See, in that regard, judgments of 25 October 2011, *Solvay* v *Commission* (C-109/10 P, EU:C:2011:686, paragraph 51), and of 25 October 2011, *Solvay* v *Commission* (C-110/10 P, EU:C:2011:687, paragraph 46); see also Opinion of Advocate General Jääskinen in *Denmark* v *Commission* (C-417/12 P, EU:C:2014:286, point 55).

22 See, for example, judgment of 25 July 2018, *Commission* v *Spain and Others* (C-128/16 P, EU:C:2018:591, paragraph 31).

23 See, for example, judgment of 6 September 2018, *Czech Republic* v *Commission* (C-4/17 P, EU:C:2018:678, paragraph 24).

reasonable standard of proof that the Commission must carry out its obligation to establish, having regard to the information put forward in the authorisation procedure, the lack of suitable alternatives under Article 60(4) of the REACH Regulation. Indeed, the General Court held, in paragraph 86 of the judgment under appeal, that the Commission had failed to verify significant information before granting the authorisation so as to be able to conclude that alternatives were lacking for all the uses applied or that the remaining uncertainties were 'negligible'.

58. In that regard, as is apparent from paragraph 77 of the judgment under appeal, the General Court's finding in paragraph 79 of the judgment under appeal that the applicant for authorisation bears the risk of any impossibility of establishing the unavailability of alternatives and therefore, where uncertainties remain, he cannot be granted an authorisation flows from the wording of Article 60(4) of the REACH Regulation, read in conjunction with recital 69 thereof, according to which the applicant for authorisation has the burden of proof in that regard and thus bears the risk where that requirement remains unproven.

59. Likewise, as indicated by the Kingdom of Sweden, the General Court's finding in paragraph 81 of the judgment under appeal that the Commission cannot adopt an authorisation decision on the basis of mere hypotheses cannot be read as imposing an impossible standard of proof on it. It follows from that finding that if there are only assumptions about the unavailability of suitable alternatives, that requirement has not been established, whereas if the Commission has information that supports the claim that there are no suitable alternatives, that requirement is met.

60. It should also be pointed out that, in paragraph 85 of the judgment under appeal, read together with paragraph 84 thereof, the General Court, correctly in my view, held that if the evidence provided by the applicant for authorisation in its analysis of alternatives is contradicted by the evidence submitted by third parties or Member States, the Commission must examine the requirement concerning the lack of availability of alternatives in greater depth, such that if uncertainties still remain following such an examination, that requirement is not fulfilled and the Commission is not entitled to grant an authorisation.

61. It was on that basis that the General Court found, in paragraph 86 of the judgment under appeal, that, on the date of adoption of the decision at issue, the Commission had not duly completed its examination of the lack of availability of alternatives, and that in the absence of a more in-depth examination of that requirement, the authorisation could not be granted. It is clear that that finding was based on several considerations, set out in paragraphs 87 to 98 of the judgment under appeal.

62. In particular, the General Court held, in paragraph 90 of the judgment under appeal, read together with paragraphs 88 and 89 thereof, that information submitted by one stakeholder cast doubt on the applicant's assertion in its analysis of alternatives that the substances at issue were characterised by a high technical performance which was not matched by any of the alternatives.

63. The General Court also rejected, in paragraph 101 of the judgment under appeal, the Commission's argument that it carried out further analyses of the lack of suitable alternatives, on the ground that such analyses consisted of additional information from the applicant which did not clarify the uses for which there were no alternatives.

64. In those circumstances, the Commission's arguments concerning its application of a zero threshold for technical feasibility of alternatives are unpersuasive, as the General Court did not take a position on the matter in the paragraphs of the judgment under appeal challenged by the Commission. Irrespective of the Commission's application of such a threshold, arguments to that effect do not substantiate the claim that the General Court imposed an impossible standard of proof under Article 60(4) of the REACH Regulation. As is apparent from paragraphs 86, 90 and 101 of the judgment under appeal, the

General Court, rightly in my view, considered, having regard to information relating to the technical performance of the substances at issue, that there was clear evidence that the Commission's assessment of the lack of availability of alternatives had not been completed and that the Commission had not sufficiently explained why it considered the alternatives unsuitable.

65. I therefore propose that the first ground of appeal should be rejected as unfounded.

B. Second ground of appeal (relating to the zero threshold for technical feasibility of alternatives)

1. Summary of the arguments of the parties

66. By the second ground of appeal, the Commission, supported generally by ECHA, claims, in essence, that the General Court committed a manifest error of law, in paragraphs 86, 90 and 96 of the judgment of appeal, by disregarding the Commission's discretionary powers to set a threshold value for technical and economic feasibility when assessing alternatives under Article 60(4) of the REACH Regulation. In consequence of this, it takes the view that the General Court applied an incorrect criterion for judicial review and substituted itself for the Commission in weighing up the relevant social, economic and technical considerations.

67. The Commission argues that the decision at issue is based on its application of a zero threshold for loss of technical performance and that no alternative met that threshold. In its view, the General Court's approach failed to take this into account and confused those two elements. According to the Commission, it did not err by setting a zero threshold and then assessing the alternatives in light of that threshold, since it is impossible to assess the technical feasibility of an alternative without deciding what level of loss of performance can be regarded as acceptable, which similarly applies for economic feasibility. That decision falls within the Commission's discretion, requiring it to balance various considerations. That is why, it contends, its assessment of alternatives falls within the scope of judicial review based on manifest error, as the General Court correctly held in its judgment of 4 April 2019, *ClientEarth* v *Commission* (T-108/17, EU:T:2019:215), but which it failed to apply in the judgment under appeal.

68. The Kingdom of Sweden, supported by the Kingdom of Denmark, asserts that the second ground of appeal is inadmissible for two reasons. First, the General Court's findings complained of concern a question of fact. Second, the Commission's application of a zero threshold for technical feasibility of alternatives was not relied on before the General Court and thus constitutes a new argument, which cannot be invoked on appeal.

69. The Kingdom of Sweden, supported by the Kingdom of Denmark, the Republic of Finland and the Parliament, further contends that the second ground of appeal is unfounded.

70. First, the Kingdom of Sweden and the Parliament argue that the Commission's zero-threshold approach is not apparent from the decision at issue, nor did the Commission raise this argument before the General Court. Thus, the Kingdom of Sweden asserts that there is no evidence to substantiate the Commission's claim that the General Court did not take that matter into account or that it disregarded the Commission's discretionary powers. The Parliament submits that, while this argument amounts to a purely 'retroactive reconstruction', it is, in any event, irrelevant whether the Commission fixed such a threshold, since the General Court based its findings on the fact that the Commission was not in the position to establish definitively the lack of availability of alternatives, and it admits in the decision at issue that it is not clear whether there are any alternatives which meet the criteria set.

71. Second, the Kingdom of Sweden, together with the Kingdom of Denmark, the Republic of Finland and the Parliament, claims that the Commission's zero-threshold approach is contrary to the REACH Regulation. The Kingdom of Sweden maintains that the General Court correctly held that alternatives must be assessed concretely in terms of their intended use and thus, by establishing a threshold for loss of performance without taking into account the function for which that performance is necessary as regards the intended use, the Commission did not comply with Article 60(4) of the REACH Regulation. The Kingdom of Denmark and the Parliament emphasise that such an approach is not in line with the wording and objectives of the REACH Regulation and is liable to empty the requirement concerning the unavailability of alternatives of its substance, since it restricts substitution based on alternatives with equivalent characteristics to the substance in question. The Republic of Finland also considers that technical performance should be assessed separately for each use and the Commission's approach leads to authorising substances of very high concern too easily, which undermines the authorisation regime.

2. Assessment of the second ground of appeal

(a) Admissibility

72. First, the Kingdom of Sweden, together with the Kingdom of Denmark, essentially challenges the admissibility of the second ground of appeal on the ground that it concerns the General Court's assessment of the facts and evidence on the basis of which it found that the Commission had not duly established the lack of availability of alternatives, which, in the absence of allegations that the facts and evidence are distorted, cannot be reviewed by the Court of Justice on appeal.

73. I disagree with that plea of inadmissibility. As I advanced in point 50 of this Opinion, the question whether the General Court could correctly conclude based on the facts and evidence before it that the Commission erred in its assessment of the lack of suitable alternatives concerns the legal characterisation of the facts of the case, which the Court of Justice has jurisdiction to review on appeal.

74. Second, the Kingdom of Sweden, together with the Kingdom of Denmark, challenges the admissibility of the second ground of appeal on the ground that the Commission's allegations concerning its application of a zero threshold for technical feasibility of alternatives is a new argument which was not raised before the General Court and thus cannot be considered by the Court of Justice on appeal.

75. I also disagree with that plea of inadmissibility. On the basis of the analysis propounded in point 52 of this Opinion, the Commission's argument concerning its application of a zero threshold for technical feasibility of alternatives should be considered admissible in accordance with the Court's case-law, since it is intended to challenge the correctness, in law, of the General Court's findings that the Commission failed to carry out a proper assessment of the lack of suitable alternatives under Article 60(4) of the REACH Regulation, and it is based on arguments raised by the Commission in the proceedings before the General Court.

76. Thus, I consider that the second ground of appeal is admissible.

(b) Substance

77. By the second ground of appeal, the Commission contends that the General Court erred in law by misinterpreting the discretion that the Commission enjoys to determine the threshold for technical and economic feasibility of alternatives under Article 60(4) of the REACH Regulation and the standard of judicial review over its decisions taken pursuant to that provision.

78. As mentioned in point 61 of this Opinion, the General Court found, in paragraph 86 of the judgment under appeal, that, on the date of adoption of the decision at issue, the Commission had not duly established the lack of availability of alternatives under Article 60(4) of the REACH Regulation. That finding was based on several considerations, set out in paragraphs 87 to 98 of the judgment under appeal.

79. In particular, the General Court considered, in paragraph 90 of the judgment under appeal, that information submitted by one stakeholder indicated that, subject to certain conditions, alternatives were available on the EU market for all the uses referred to in the application for authorisation.

80. The General Court also held, in paragraph 96 of the judgment under appeal, that it was apparent from recitals 8, 9 and 12 of the decision at issue that the Commission still had doubts as to the lack of availability of technically feasible alternatives for all the uses covered by the application for authorisation.

81. In my view, no error of law is discernible in those findings.

82. First, I observe that the Commission's determination of a threshold value for technical or economic feasibility of alternatives is not mentioned in the decision at issue or in the judgment under appeal, whether in the summary of the Commission's arguments in paragraphs 51 to 56 of that judgment or in the General Court's findings. Indeed, the judgment under appeal does not take a general position on the Commission's discretionary powers to assess the technical or economic feasibility of alternatives. Consequently, as indicated by the Kingdom of Sweden and the Parliament, there appears to be no evidence to substantiate the Commission's claim that the General Court erred by failing to take into account its application of a zero threshold for technical performance in the decision at issue or disregarding its discretionary powers to set thresholds for technical and economic feasibility of alternatives.

83. Moreover, the General Court's finding, in paragraph 96 of the judgment under appeal, as regards recitals 8, 9 and 12 of the decision at issue does not seem to me to be open to criticism. As seen in points 24 and 25 of this Opinion, in recitals 8, 9 and 12 of the decision at issue, the Commission recognised 'the difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope' of the uses covered by the application. Thus, the General Court's finding follows from the wording of those recitals. The Commission's allegations that it applied a zero threshold for technical feasibility and found that no alternatives met that threshold do not invalidate this.

84. That said, in so far as the Commission alleges that its application of a zero threshold for technical feasibility of alternatives is a basis for the decision at issue, this raises the question whether such an approach is in conformity with the REACH Regulation. My understanding of that approach is that a suitable alternative is technically feasible only if it offers, for the intended uses, the same technical performance as the substances at issue. On that basis, it seems to me that, as indicated by the Kingdom of Denmark, the Republic of Finland, the Kingdom of Sweden and the Parliament, there are strong indications, in light of the wording and objectives of the REACH Regulation, that such an approach is not consistent with the authorisation regime established by that regulation. Nor is it consistent with the judgment under appeal.

85. In that regard, it should be pointed out that the General Court set out its interpretation, in paragraphs 70 to 76 of the judgment under appeal, of the concept of a suitable alternative for the purposes of the REACH Regulation. In particular, it noted that, according to a guidance document issued by ECHA, an alternative denotes a possible replacement for the substance in question, and which should be able to replace the function that that substance performs. In its view, the notion of suitable alternative is one which is not only safer, but also 'economically and technically viable' within the meaning of Article 55 of the REACH Regulation. That phrase implies, according to the General Court, that suitable alternatives are not limited to the existence of alternative substances or

technologies in the abstract or under conditions which are only of an exceptional nature, but that the assessment must be carried out from the perspective of the production capacities for those substances, the feasibility of those technologies and the legal and factual requirements for putting them into circulation.

86. The General Court further noted that the assessment of suitable alternatives also involves a subjective criterion as to whether the alternatives are technically and economically feasible 'for the applicant' for authorisation under Article 60(5)(b) of the REACH Regulation, such that where an alternative is available in general, but not yet for an applicant, authorisation may still be granted if that applicant submits a substitution plan, as provided in that regulation, for the eventual replacement of the substance with the alternative.

87. It follows from the judgment under appeal that the requirement relating to the lack of suitable alternatives under Article 60(4) of the REACH Regulation entails a concrete assessment, taking account of objective and subjective criteria, as regards the capacities of the alternative to replace the function that the substance of very high concern performs in relation to the uses intended by the applicant for authorisation.

88. It should also be pointed out that, while there are no definitions in the REACH Regulation relating to the concepts of suitable alternative or technical and economic feasibility, it may be inferred from the wording of the REACH Regulation, namely that alternatives for the purposes of Article 60(4) and (5) of that regulation must be 'suitable' and 'feasible', that they must be able, based on a reasonable assessment of cost, availability and efficacy, to carry out the function served by the substance in question.[24] This is supported in particular by Article 60(4)(d) ('any alternative substances or technologies') and Article 60(5) ('all relevant aspects') of the REACH Regulation, which evince a broad notion of a suitable alternative which may be capable of replacing the substance, and is not limited merely to exact ('drop in') substitutes. This is also echoed in ECHA guidance documents, indicating that technical feasibility of an alternative is based on the alternative fulfilling or replacing the function that the substance performs, whereas economic feasibility focuses on the changes in the costs and revenues of the applicant for authorisation as a result of the transfer to the alternative.[25]

89. Moreover, the assessment of the lack of suitable alternatives should take account, in particular, of the objective pursued by the REACH Regulation to ensure a high level of human health and environmental protection under Article 1(1) of that regulation, along with the specific objective of the authorisation regime, set out in Article 55 thereof, to ensure that substances of very high concern are progressively replaced by suitable alternatives where they are economically and technically viable (see points 9 and 10 of this Opinion).

90. In light of those considerations, the Commission's application of a zero threshold for technical feasibility of alternatives as described in point 84 of this Opinion does not seem to me to be consistent with the broad notion of suitable alternatives reflected in the REACH Regulation and the General Court's findings that the assessment of suitable alternatives must be assessed concretely in light of the relevant circumstances and capacities of the alternative to carry out the function of the substance for the uses applied for. By establishing a threshold for loss of technical performance without taking account of the function to be fulfilled by the substance for which that performance is necessary in the uses applied for, such an approach disregards the fact that technical feasibility of the alternative should be assessed against the function to be performed for the intended use and not

24 See, in that regard, Commission Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}, COM(2003) 644 final, 29 October 2003, Explanatory Memorandum, draft Article 57, second paragraph.

25 See, for example, ECHA, *Guidance on the preparation of an application for authorisation* (OJ 2011 C 28, p. 1), in particular points 3.6 and 3.8. See also, more recently, ECHA, *How to apply for authorisation*, October 2017, available at https://echa.europa.eu/, point 3.3.

against the performance of the substance of very high concern. As a consequence, that approach may be liable to empty the requirement relating to the lack of suitable alternatives under Article 60(4) of the REACH Regulation of its substance, since it impermissibly restricts the range of potential alternatives.

91. Such an approach thus appears to conflict with the objective of the REACH Regulation to protect human health and the environment in so far as it may lead to the granting of authorisations in situations where suitable alternatives may in fact be available. By the same token, it undermines the objective of the authorisation regime in Article 55 of the REACH Regulation to promote the progressive replacement of substances of very high concern, given that it may lead to the possibility of substitution being allowed only in the exceptional cases where it does not lead to any loss of efficacy.

92. Finally, in my view, the complaints based on the standard of judicial review of the decision at issue are not convincing. In particular, the Commission's reference to the General Court's judgment of 4 April 2019, *ClientEarth* v *Commission* (T-108/17, EU:T:2019:215)[26] appears to me to be misplaced. As indicated by the Republic of Finland, the circumstances arising in the present case differ from those arising in that judgment, especially since it did not concern the General Court's review of a Commission authorisation decision based on the REACH Regulation, but rather a Commission decision rejecting a request for internal review of the authorisation decision under Article 10 of Regulation No 1367/2006, which implements the obligations contained in the Aarhus Convention.[27]

93. In addition, in that judgment, the General Court held that its review for manifest error relates to an EU institution's assessment of complex facts, such that the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act adopted by that institution implausible.[28] In contrast, the contested paragraphs of the judgment under appeal are not concerned with the plausibility of the Commission's factual assessments as the basis for authorisation, but rather with the failure to comply with its assessment obligation to establish the lack of suitable alternatives under Article 60(4) of the REACH Regulation. Similarly, I fail to see any basis for the claim that the General Court substituted itself for the Commission in assessing the availability of alternatives, since the General Court did not rule on that question in those paragraphs.

94. I therefore propose that the second ground of appeal should be rejected as unfounded.

C. Third ground of appeal (relating to the partial scope and conditions of authorisation in the decision at issue)

1. Summary of the arguments of the parties

95. By the third ground of appeal, the Commission, supported generally by ECHA, asserts that the General Court committed a manifest error of law, in paragraphs 86, 97 and 98 of the judgment under appeal, as regards the decision at issue. This ground is divided into two parts.

26 An appeal against that judgment is pending: see footnote 3 of this Opinion.

27 Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ 2006 L 264, p. 13).

28 See judgment of 4 April 2019, *ClientEarth* v *Commission* (T-108/17, EU:T:2019:215, in particular paragraphs 246, 248, 249 and 259 to 262).

96. By the first part of the third ground of appeal, the Commission claims that the General Court failed to take into account that the decision at issue did not authorise all the uses referred to in the application for authorisation, but rather constituted a partial authorisation for certain uses of the substances at issue in which the technical performance properties of those substances were necessary for the intended use. It thus argues that the decision at issue could not be interpreted as meaning that the requirements of Article 60(4) of the REACH Regulation were not met for partial authorisation.

97. By the second part of the third ground of appeal, the Commission disputes the General Court's finding that certain conditions in the decision at issue indicated that the assessment of the lack of availability of alternatives in Article 60(4) of the REACH Regulation had not been completed. In its view, it is possible to limit the scope of authorisation by means of objective criteria and to define the authorised uses by reference to the functionalities sought, as was done in Article 1(1) and (2) of the decision at issue. According to the Commission, the conditions set out in Article 1(3)(d) and (e) of that decision concerning reporting requirements for the authorisation holder and its downstream users were intended to improve the information available to ECHA and the Commission at the review stage or even earlier. It also asserts that it did not delegate to the Member State competent authorities the discretionary task of assessing alternatives by virtue of Article 3(b) of the decision at issue. Having regard to the provisions of the REACH Regulation concerning the role of the Member States in the implementation and enforcement of that regulation, such as Articles 122, 125 and 126 and recitals 119 to 121 thereof, it considers that not allowing the Member States to carry out compliance monitoring and verification tasks in the context of authorisation disregards the division of competences provided for in that regulation and could have adverse effects on human health and the environment.

98. The Kingdom of Denmark argues that the third ground of appeal is inadmissible because it is based on the General Court's assessment of the facts and evidence, which cannot be reviewed on appeal.

99. The Kingdom of Sweden, supported by the Kingdom of Denmark, the Republic of Finland and the Parliament, further contends that the third ground of appeal is unfounded. They take the view that the General Court correctly held that the Commission failed to reach a conclusion regarding the lack of availability of alternatives, as is apparent from the conditions in the decision at issue requiring the authorisation holder and its downstream users to provide information on the availability of suitable alternatives and the downstream users to refrain from using the substances at issue in the event that they identified an alternative. They emphasise that, while it may be possible to limit the scope of authorisation by objective criteria, the Commission cannot formulate conditions which represent the requirements which it is responsible for assessing under Article 60(4) of the REACH Regulation. The Kingdom of Sweden also submits that the Commission cannot delegate to Member State competent authorities the tasks entrusted to it under the REACH Regulation; those authorities have the power to enforce authorisation decisions, but they cannot take a position on whether the requirements in Article 60(4) thereof are met.

2. Assessment of the third ground of appeal

(a) Admissibility

100. The Kingdom of Denmark essentially challenges the admissibility of the third ground of appeal on the ground that it concerns the General Court's factual assessment on the basis of which it found that the Commission had not duly established the lack of availability of alternatives under Article 60(4) of the REACH Regulation, which cannot be reviewed by the Court of Justice on appeal.

101. In my view, that plea of inadmissibility cannot succeed. As noted in points 50 and 73 of this Opinion, the question whether the General Court could correctly conclude on the basis of the facts and evidence before it that the Commission erred in its assessment of the lack of suitable alternatives concerns the legal characterisation of the facts of the case, which the Court of Justice has jurisdiction to review on appeal.

102. Thus, I consider that the third ground of appeal is admissible.

(b) Substance

103. By the third ground of appeal, the Commission claims that the General Court erred in law in misapplying Article 60(4) of the REACH Regulation to the decision at issue. In the first part of this ground, the Commission argues that the General Court wrongly considered that it had authorised all the uses referred to in the application for authorisation, whereas it had granted only a partial authorisation. In the second part of this ground, the Commission criticises the General Court's findings that certain conditions in the decision at issue evidenced that it had granted the authorisation before having carried out a sufficient examination of the lack of availability of alternatives.

104. It should be noted at the outset that the first part of the third ground of appeal seems to me to be lacking in fact. Contrary to what the Commission contends, the General Court found, in paragraph 97 of the judgment under appeal, read in conjunction with paragraphs 54 to 56 thereof, that the decision at issue did not authorise all the uses requested, but was 'limited solely to those cases' in which the performance characteristics of the substances at issue were necessary.

105. Nevertheless, it is true that, as the Commission alleges in the first and second parts of the third ground of appeal, the General Court held, in paragraphs 97 and 98 of the judgment under appeal, that the conditions which the Commission attached to the authorisation supported its finding, in paragraph 86 of the judgment under appeal, that the Commission had not duly established the lack of availability of alternatives on the date of adoption of the decision at issue.

106. The General Court ruled, in paragraph 97 of the judgment under appeal, that the condition in Article 1(1) and (2) of the decision at issue, under which the Commission limited the authorisation to those cases in which the performance of the compositions containing the substances at issue was really necessary, amounted to a declaration that a downstream user, whenever he identified an alternative, should refrain from using the substances at issue. The General Court took the view that that condition was a strong indication that, at the time of the adoption of the decision at issue, the Commission did not consider that the examination of the lack of availability of alternatives had been completed.

107. The General Court further held, in paragraph 98 of the judgment under appeal, that the conditions in Article 1(3)(d) and (e) of the decision at issue, under which the authorisation holder's downstream users had to supply information concerning suitable and available alternatives that provided a detailed justification of the need to use the substances at issue and the authorisation holder had to present a report in which it was to refine the description of the authorised uses based on the alternatives provided by its downstream users, were evidence that the Commission's examination of the lack of availability of alternatives had not yet been completed.

108. In my view, those findings are not vitiated by an error of law.

109. It should be recalled that, under Article 60(4) of the REACH Regulation, the lack of suitable alternatives is a precondition for authorisation granted under that provision and thus the assessment of that requirement must have been completed before the decision at issue was taken. While the REACH Regulation generally requires that conditions be placed on authorisations (see point 13 of this

Opinion) and does not appear to preclude, as the Commission points out, limiting the scope of authorisation by objective criteria, it follows from Article 60(4) of the REACH Regulation that the Commission cannot make an authorisation subject to conditions which it is required to assess under that provision. As the General Court, correctly in my view, held in paragraphs 82 and 83 of the judgment under appeal, the possibility of attaching conditions to an authorisation cannot be used in particular as a means to allow the Commission to leave open the question whether the requirements of Article 60(4) of the REACH Regulation have been met or to remedy deficiencies in the assessment it must carry out under that provision.

110. Consequently, it seems to me that the Commission is not entitled under Article 60(4) of the REACH Regulation to make an authorisation subject to the requirement that there are no suitable alternatives to a given substance, which is reflected in the condition in Article 1(1) and (2) of the decision at issue that the performance must be technically viable only by use of the substances at issue and that this performance is necessary for the intended use (see point 26 of this Opinion). In my view, that condition essentially leaves it to the authorisation holder and its downstream users to decide for themselves whether there is a suitable alternative. Therefore, as the General Court correctly held, that condition implies that the Commission had not completed the assessment required under Article 60(4) of the REACH Regulation.

111. I am also in agreement with the General Court's reading of the conditions in Article 1(3)(d) and (e) of the decision at issue. Article 1(3)(d) of that decision in particular obliges downstream users to provide information on the availability of alternatives and justify the need to use the substances at issue, while Article 1(3)(e) of that decision obliges the authorisation holder to report on that information submitted by its downstream users and to refine the description of the authorised uses based on that information (see points 27 and 28 of this Opinion). In my view, those conditions in substance amount to asking the authorisation holder and its downstream users to provide information intended to assess the lack of availability of alternatives for the uses of the substances at issue after those uses have been authorised by the Commission. Thus, it seems to me that that condition, too, indicates that the Commission's assessment of lack of availability of alternatives had not been completed.

112. It might be added that similar conclusions can be drawn with regard to Article 3(b) of the decision at issue, which states that, at the request of the relevant Member State competent authority, the authorisation holder's downstream users must substantiate why the conditions of Article 1(1) and (2) of that decision apply and why the performance parameters are necessary for the intended use (see point 29 of this Opinion). To my mind, it essentially provides for the Member State competent authorities to verify whether downstream users correctly determined that there are no suitable alternatives for the uses of the substances at issue. Thus, it can be considered to substantiate further that the Commission's assessment of the lack of availability of alternatives had not been completed. Contrary to the Commission's arguments, there is nothing to suggest from the provisions of the REACH Regulation concerning the role of the Member States in the implementation and enforcement of that regulation that they can carry out tasks which fall within the Commission's assessment obligation under Article 60(4) of the REACH Regulation.

113. I therefore propose that the third ground of appeal should be rejected as unfounded.

D. Fourth ground of appeal (relating to the maintenance of the effects of the decision at issue)

1. Summary of the arguments of the parties

114. By the fourth ground of appeal, submitted in the alternative, the Commission, supported generally by ECHA, contends that point 2 of the operative part of the judgment under appeal, by which the General Court refused to maintain the effects of the decision at issue, is based on a manifest error of law in paragraph 112 of that judgment.

115. First, the Commission argues that paragraph 112 of the judgment under appeal is based on an incorrect premiss – which it admits was also made in its written submissions before the General Court – that the annulment of the decision at issue results in prohibiting the placement of the substances at issue on the market. In its view, the annulment of the decision at issue has the effect of restoring the legal situation existing before its adoption, which means that, having regard to the transitional rules in Article 56(1)(d) of the REACH Regulation, the substances at issue can continue to be used and placed on the market by the applicant and its downstream users for the uses requested until the Commission takes a new decision on the application for authorisation.

116. Second, the Commission claims that the immediate effect of the annulment of the decision at issue poses a significantly increased risk to human health and the environment, given that the substances at issue could be used and placed on the market without being subject to the conditions and limitations laid down in the decision at issue. It therefore asserts that, even if the other grounds of appeal are rejected, the Court should set aside point 2 of the operative part of the judgment under appeal and maintain the effects of the decision at issue until it is replaced by a new decision.

117. The Kingdom of Sweden, supported by the Kingdom of Denmark and the Republic of Finland, contends that the fourth ground of appeal is unfounded.

118. The Kingdom of Sweden, together with the Republic of Finland, claims that, although the effects of the annulment of the decision at issue are different from those foreseen by the General Court, its rejection of the Commission's request is well founded because the conditions for maintaining the effects of the decision at issue are not met. In particular, those Member States assert that the annulment of that decision does not entail serious consequences for DCC Maastricht, given that it can continue to market the substances at issue for the uses requested until the Commission takes a new decision. It also does not pose risks to human health and the environment, since there are EU rules in place to protect workers from exposure to the substances at issue.[29] Nor has the Commission shown that the quantities authorised by the decision at issue are lower than those referred to in the application for authorisation.

119. The Kingdom of Denmark argues that the transitional rules in Article 56(1)(d) of the REACH Regulation lapse once the Commission takes its decision and cannot be revived where that decision is annulled, as in the present case, since that would run counter to the objective to ensure a high level of human health and environmental protection pursued by that regulation. In its view, that provision establishes an exception to the general prohibition on the use and placement on the market of substances of very high concern and thus must be interpreted restrictively.

29 Those Member States refer, in that regard, to Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ 1992 L 348, p. 1); Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ 1998 L 131, p. 11); and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ 2004 L 158, p. 50).

2. Assessment of the fourth ground of appeal

120. By the fourth ground of appeal, submitted in the alternative, the Commission contends that the General Court erred in law in refusing its request to maintain the effects of the decision at issue. It requests that the Court set aside point 2 of the operative part of the judgment under appeal and maintain the effects of the decision at issue until the Commission takes a new decision on the application for authorisation.

121. It should be observed that it will only be necessary for the Court to rule on this ground of appeal if it rejects the other grounds of appeal and upholds the annulment of the decision at issue, as I propose.

122. I wish to state at the outset that the fourth ground of appeal is well founded. My reasons for reaching that conclusion are as follows.

123. It should be borne in mind that the annulment of an EU act generally results in its elimination from the EU legal order from the date when that act entered into force, that is to say, it has retroactive (*ex tunc*) effects.[30] Yet, under settled case-law, which was mentioned in paragraphs 109 to 111 of the judgment under appeal, the second paragraph of Article 264 TFEU permits the EU Courts to attenuate the retroactive effects of annulment by providing that they may, if they consider this necessary, state which of the effects of the act declared void are to be considered as definitive. That provision has been interpreted, inter alia, as allowing, on grounds of legal certainty as well as on grounds seeking to prevent a decline in EU policies, such as in the fields of public health and environmental protection, the effects of an EU act declared void to be maintained until the EU institution or body concerned adopts appropriate measures.[31]

124. The General Court held, in paragraph 112 of the judgment under appeal, that the annulment with immediate effect of the decision at issue was likely to give rise to serious negative consequences for DCC Maastricht, since it would no longer be able to market the substances at issue. However, it pointed out that the annulment of the decision at issue was based on grounds relating to its substantive legality. It also took the view that the maintenance of the effects of that decision was not compatible with the objective of the REACH Regulation to ensure a high level of human health and environmental protection. On that basis, the General Court refused, in point 2 of the operative part of the judgment under appeal, to maintain the effects of the decision at issue.

125. In my view, the General Court's finding in paragraph 112 of the judgment under appeal is vitiated by an error of law.

126. It should be considered that the annulment of the decision at issue had the effect of reverting to the transitional rules in Article 56(1)(d), read together with Article 58(1)(c)(ii), of the REACH Regulation, which state that an applicant may continue to place the substance in question on the market for the uses requested after the sunset date until a decision is taken on the application for authorisation, provided that that application was submitted by the latest application date for the substance listed in Annex XIV to that regulation (see points 5, 6 and 12 of this Opinion).

30 See, for example, judgments of 26 April 1988, *Asteris and Others* v *Commission* (97/86, 99/86, 193/86 and 215/86, EU:C:1988:199, paragraph 30), and of 12 February 2008, *CELF and ministre de la Culture et de la Communication* (C-199/06, EU:C:2008:79, paragraph 61).

31 See, for example, judgments of 25 February 1999, *Parliament* v *Council* (C-164/97 and C-165/97, EU:C:1999:99, paragraphs 22 to 24); of 16 April 2015, *Parliament* v *Council* (C-317/13 and C-679/13, EU:C:2015:223, paragraphs 72 to 74); and of 13 December 2018, *Ville de Paris, Ville de Bruxelles and Ayuntamiento de Madrid* v *Commission* (T-339/16, T-352/16 and T-391/16, EU:T:2018:927, paragraph 160). For a detailed discussion, see, for example, Rosenkranz, F., 'Temporal Effects of CJEU Judgments', in Riesenhuber, K. (ed.), *European Legal Methodology*, Intersentia, 2017, pp. 561-590.

127. In the present case, DCC Maastricht, having applied for authorisation within the prescribed time limit, benefited from those transitional rules (see points 18, 19 and 23 of this Opinion). Since the annulment of the decision at issue had the effect of requiring the Commission to reconsider the application for authorisation, it seems to me that DCC Maastricht regains the benefit of those transitional rules until the Commission takes a new decision on that application. Contrary to the arguments submitted by the Kingdom of Denmark, there is nothing to suggest from the wording of those provisions that they do not apply in the situation where an authorisation decision has been annulled.

128. Thus, it seems to me that the General Court erred in law in paragraph 112 of the judgment under appeal by failing to have regard to the transitional rules in Articles 56(1)(d) and 58(1)(c)(ii) of the REACH Regulation.

129. Furthermore, it is true that, under the settled case-law referred to in paragraph 111 of the judgment under appeal, the Court has held that, on grounds of legal certainty, the effects of an EU act declared void may be maintained in particular where the lawfulness of that act is contested, not because of its aim or content, but on grounds of lack of competence or infringement of an essential procedural requirement.[32] However, a close reading of the Court's case-law reveals that, while that element may be considered an obstacle to prevent the Court from ordering that the effects of an EU act be maintained in some cases,[33] in others, the Court has maintained the effects of an EU act which was annulled on grounds relating to its substantive legality.[34] Thus, it appears from the Court's case-law so far that that element is not a requirement which must be met in every case, but rather depends on the particular situation.

130. In my view, it cannot be excluded in the circumstances of the present case that the rejection of the Commission's request to maintain the effects of the decision at issue may pose risks to human health and the environment. Contrary to the arguments advanced by the Republic of Finland and the Kingdom of Sweden, the decision at issue establishes conditions and limitations which effectively restrict the use of the substances at issue apart from the EU rules protecting workers from exposure to those substances referred to in point 118 of this Opinion. This includes, inter alia, the specific programme on personal protective equipment and employee training mentioned in Article 1(3)(b) and recital 10 of the decision at issue, along with the annual tonnage limits, referred to in Article 1(3)(c) and recital 13 of that decision, to ensure that the quantities of the substances at issue do not exceed those reported in the application for authorisation. Moreover, the time-limited review periods in Article 2 of the decision at issue would be removed.[35] Thus, on balance, it is preferable for the protection of human health and the environment to maintain the effects of the decision at issue.

131. I therefore propose that the Court should set aside point 2 of the operative part of the judgment under appeal and order that the effects of the decision at issue be maintained until the Commission takes a new decision on the application for authorisation.

32 See, for example, judgments of 26 November 2014, *Parliament and Commission* v *Council* (C-103/12 and C-165/12, EU:C:2014:2400, paragraph 90), and of 28 July 2016, *Council* v *Commission* (C-660/13, EU:C:2016:616, paragraph 51).

33 See, for example, judgments of 1 December 2015, *Parliament and Commission* v *Council* (C-124/13 and C-125/13, EU:C:2015:790, paragraph 89), and of 7 September 2016, *Germany* v *Parliament and Council* (C-113/14, EU:C:2016:635, paragraph 84).

34 See, for example, judgments of 7 September 2006, *Spain* v *Council* (C-310/04, EU:C:2006:521, paragraphs 138 to 141, read together with paragraphs 135 to 137), and of 3 September 2008, *Kadi and Al Barakaat International Foundation* v *Council and Commission* (C-402/05 P and C-415/05 P, EU:C:2008:461, paragraphs 373 to 376, read together with paragraphs 333 to 372).

35 See, in that regard, order of the Vice-President of the Court of 21 November 2019, *Commission* v *Sweden* (C-389/19 P-R, not published, EU:C:2019:1007, paragraphs 77 to 80).

VII. Costs

132. Under Article 184(2) of its Rules of Procedure, where the appeal is unfounded or where the appeal is well founded and the Court itself gives final judgment in the case, the Court is to make a decision as to costs. Pursuant to Article 138(3) of those rules, which applies to appeals by virtue of Article 184(1) thereof, where each party succeeds on some and fails on other heads, the parties are to bear their own costs. However, if it appears justified in the circumstances of the case, the Court may order that one party, in addition to bearing its own costs, pay a proportion of the costs of the other party. As the Commission has been successful only as regards the subsidiary form of order which it sought, it would appear reasonable for the Commission to bear four fifths of the costs incurred by the Kingdom of Sweden, while the Kingdom of Sweden should bear one fifth of the costs incurred by the Commission.

133. Under Article 140(1) of the Rules of Procedure, which applies to appeals by virtue of Article 184(1) thereof, Member States and EU institutions which have intervened in the proceedings are to bear their own costs. Under Article 184(4) of those rules, the Court may decide that an intervener at first instance who takes part in the appeal is to bear its own costs. Accordingly, the Kingdom of Denmark, the Republic of Finland, the Parliament and ECHA must bear their own costs.

VIII. Conclusion

134. In light of the foregoing, I propose that the Court should:

– set aside point 2 of the operative part of the judgment of 7 March 2019, *Sweden* v *Commission* (T-837/16, EU:T:2019:144);

– dismiss the appeal as to the remainder;

– order the European Commission to bear four fifths of its own costs and to pay four fifths of the costs incurred by the Kingdom of Sweden;

– order the Kingdom of Sweden to bear one fifth of its own costs and to pay one fifth of the costs incurred by the European Commission; and

– order the Kingdom of Denmark, the Republic of Finland, the European Parliament and the European Chemicals Agency to bear their own costs.