OPINION OF ADVOCATE GENERAL
KOKOTT
delivered on 25 February 2021 (1)

Case C-458/19 P

ClientEarth
v
European Commission

(Appeal – Action for annulment – Regulation (EC) No 1367/2006 – Aarhus Convention – Access to justice in environmental matters – Internal review – Rejection – Subject of the review – Regulation (EC) No 1907/2006 – Registration, Evaluation, Authorisation and Restriction of Chemicals – Authorisation requirement – Implementing decision C(2016) 3549 final granting an authorisation for uses of bis(2-ethylhexyl) phthalate (DEHP) – Overriding socio-economic benefits – Consideration of risks)

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I. Introduction

1. Bis(2-ethylhexyl) phthalate (DEHP) is a ‘plasticiser’ which is added to polyvinyl chloride (PVC) plastics. Serious risks to human health are associated with DEHP. The use of the substance therefore requires an authorisation under the REACH Regulation, (2) to be decided by the Commission upon application by the user.

2. ClientEarth is a non-governmental organisation (NGO) focusing on the protection of the environment. In these proceedings, it is, as a third party, challenging one such authorisation granted by the Commission to three recycling companies for the use of recycled PVC waste (PVC recyclate) containing DEHP. ClientEarth made a request to the Commission pursuant to the Aarhus Regulation (3) for a review of the authorisation and then unsuccessfully contested the rejection of that request before the General Court.

3. The present appeal therefore gives the Court of Justice a first opportunity to answer certain questions relating to the review procedure under the Aarhus Regulation and the authorisation procedure under the REACH Regulation. In essence, it concerns the verification of the balancing exercise on which the authorisation is based, and thus the factors to be taken into account, and the verification of the analysis of alternatives. There is also disagreement over the extent to which the request for review delimits the subject matter of the dispute and the extent to which third parties are able to rely on deficiencies in the application for authorisation submitted by the user in order to challenge the validity of the authorisation decision.

II. Legal framework

A. Aarhus Convention

4. Article 9(3) of the Aarhus Convention (4) provides that the Parties must give members of the public access to administrative or judicial procedures to challenge acts and omissions by private persons and public authorities which contravene provisions of its national law relating to the environment. Under Article 9(4), those procedures must provide adequate and effective remedies. The procedures must be fair, equitable, timely and not prohibitively expensive.

B. Aarhus Regulation

5. The Aarhus Regulation implements inter alia Article 9(3) of the Aarhus Convention for EU institutions and bodies. To that end, Article 10 of the Aarhus Regulation lays down an internal review procedure:

‘1. Any non-governmental organisation which meets the criteria set out in Article 11 is entitled to make a request for internal review to the Community institution or body that has adopted an administrative act under environmental law or, in case of an alleged administrative omission, should have adopted such an act.

… The request shall state the grounds for the review.

2. The Community institution or body referred to in paragraph 1 shall consider any such request … The Community institution or body shall state its reasons in a written reply … .

3. …’

6. Article 12(1) of the Aarhus Regulation refers to the possibility of instituting proceedings before the European Union Courts:

‘The non-governmental organisation which made the request for internal review pursuant to Article 10 may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty.’

7. This provision is explained in recital 21 of the Aarhus Regulation:

‘Where previous requests for internal review have been unsuccessful, the non-governmental organisation concerned should be able to institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty.’

C. REACH Regulation

8. The REACH Regulation is a comprehensive regulatory framework for the assessment and management of risks to human health and the environment arising from the manufacturing, placing on the

market and use of chemicals. For certain substances of very high concern, it restricts or even prohibits use without permission, the so-called authorisation requirement.

9. Article 3(24) of the REACH Regulation defines ‘use’ as ‘any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation’.

10. The aim of the authorisation requirement is set out in Article 55 of the REACH Regulation:

‘The aim of this Title 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. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.’

11. Under Article 56(1) of the REACH Regulation, the use of substances of very high concern included in Annex XIV requires authorisation. The properties of those substances are specified in Article 57. They include reproductive toxicity (point c) and endocrine disrupting properties (point f). Article 58 governs the procedure for inclusion in Annex XIV, which justifies the authorisation requirement.

12. An intermediate step in the procedure for establishing an authorisation requirement is provided for in Article 59 of the REACH Regulation. Under that provision, substances which may be subject to an authorisation requirement by reason of their properties of concern are identified and included in the ‘candidate list’.

13. The conditions for authorisation are laid down in Article 60 of the REACH Regulation:

‘1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.

2. Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant’s chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

The Commission shall not consider the risks to human health arising from the use of a substance in a medical device …

3. …

4. If an authorisation cannot be granted under paragraph 2 … 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.

6. A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVII.

7. An authorisation shall be granted only if the application is made in conformity with the requirements of Article 62.

8. …'

14. Article 62(4) of the REACH Regulation sets out various requirements for the application for authorisation:

'4. An application for authorisation shall include the following information:

…

(c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in mixtures and/or the incorporation of the substance in articles, where this is relevant;

(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;

(e) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;

(f) …'

15. Article 64 of the REACH Regulation regulates the authorisation procedure:

'1. …

2. The Agency shall make available on its web-site broad information on uses … for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

3. In preparing its opinion, each Committee referred to in paragraph 1 shall first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Committees shall, in consultation with each other, make a joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 62. The Committee for Socio-economic Analysis may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. Each Committee shall also take into account any information submitted by third parties.

4. The draft opinions shall include the following elements:

(a) Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;

(b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.

5. …'

16. Recital 69 of the REACH Regulation explains the authorisation requirement:

'To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorised if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. …'

17. Recital 81 of the REACH Regulation addresses the role played by third parties in the authorisation procedure:

'In order to provide a harmonised approach to the authorisation of the uses of particular substances, the Agency should issue opinions on the risks arising from those uses, including whether or not the substance is adequately controlled and on any socio-economic analysis submitted to it by third parties. These opinions should be taken into account by the Commission when considering whether or not to grant an authorisation.'

III. Facts

A. The classification of DEHP

18. By Regulation (EU) No 143/2011, (5) the Commission included DEHP, a compound essentially used to soften PVC plastics, in Annex XIV to the REACH Regulation. The Commission adopted the measure on the ground that the substance has reproductive toxicity properties within the meaning of Article 57(c) of the REACH Regulation. Since then, the use of DEHP has had to be authorised by the Commission.

19. In addition, on 26 August 2014, Denmark submitted a report according to which DEHP was also a substance of very high concern on account of endocrine disrupting properties. (6) Therefore, on 12 December 2014, the European Chemicals Agency (ECHA) updated the existing entry for DEHP in the candidate list and identified the substance as being of very high concern within the meaning of Article 57(f) of the REACH Regulation because it has endocrine disrupting properties with probable serious effects on the environment. (7) Furthermore, following the contested review of the authorisation, the Commission decided, on 4 July 2017, that such classification should also be given to DEHP on account of its endocrine disrupting effects on human health. (8) Thus far, however, the Commission has not imposed an authorisation requirement on account of the endocrine disrupting properties of DEHP.

B. The authorisation procedure

20. On 13 August 2013, three recycling companies jointly submitted an application for authorisation for the placing on the market of DEHP for the following uses:

– ‘the formulation of recycled soft poly(vinyl chloride) (PVC) containing DEHP in compounds and dry-blends,

– the industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles’.

21. The authorisation applicants do not produce DEHP, but recycle PVC waste already containing DEHP. According to the application, DEHP does not have a specific functional role for the authorisation applicants, but is a largely unwanted impurity in the recovered waste. It can nevertheless be of some benefit in the further processing of the recyclate.

22. The application was based on Article 60(2) of the REACH Regulation, claiming that the risk from use is adequately controlled.

23. On 22 October 2014, the Committee for Risk Assessment and the Committee for Socio-economic Analysis of ECHA prepared a document containing a joint and consolidated version of their opinions. (9) They concluded that an authorisation under Article 60(2) of the REACH Regulation was not possible because it had not been demonstrated that the risk from use was adequately controlled. However, socio-economic benefits outweighed the remaining risk. Accordingly, an authorisation was possible under Article 60(4).

24. On 16 June 2016, the Commission adopted Implementing Decision C(2016) 3549 final, by which it authorised the uses of DEHP applied for, with certain exceptions, on the basis of Article 60(4) of the REACH Regulation (‘the authorisation decision’).

25. In Article 2 of the authorisation decision, the Commission fixed the review period for authorisation referred to in Article 60(9)(e) of the REACH Regulation at four years from the date of expiry laid down in Annex XIV to the REACH Regulation, namely 21 February 2019.

26. In recital 8 of the authorisation decision, the Commission declared that the REACH Regulation does not apply to waste. Accordingly, ‘the authorisation to place on the market and use recycled soft PVC compounds and dry-blends containing DEHP in accordance with Article 64 of [the REACH Regulation] applie[d] to the extent that those compounds and dry-blends ha[d] ceased to be waste in accordance with Article 6 of [the Waste Directive (10)]’.

C. The review procedure

27. By letter of 2 August 2016, ClientEarth requested that the Commission carry out a review of the authorisation decision pursuant to Article 10 of the Aarhus Regulation.

28. By the contested decision C(2016) 8454 final of 7 December 2016, the Commission rejected the request for internal review on the ground that it was unfounded ('the review decision').

IV. Judicial procedure and forms of order sought

29. The General Court dismissed the action brought by ClientEarth against the contested review decision by the judgment under appeal of 4 April 2019, *ClientEarth* v *Commission* (T-108/17, EU:T:2019:215). ECHA intervened in those proceedings in support of the Commission.

30. ClientEarth has brought the present appeal and claims that the Court should:

– set aside the judgment of the General Court in Case T-108/17,

– refer the case back to the General Court for judgment,

or, alternatively,

– set aside the judgment of the General Court in Case T-108/17, and

– declare the application for annulment admissible and well-founded and, consequently, annul the contested review decision and, in any event,

– order the Commission to pay the costs, including the costs incurred by the interveners, at first instance and in appeal.

31. The Commission and ECHA contend that the Court should:

– dismiss the appeal and

– order the appellant to pay all the costs.

32. The parties have submitted written observations, although ECHA simply endorsed the submissions made by the Commission. The Court did not consider it necessary to hold a hearing.

33. Upon the request of the Court, the parties indicated that one of the applicant companies has submitted a review report and thus requested the extension of the authorisation decision, whilst the other two companies have not done so.

V. Legal assessment

34. This appeal concerns the interaction between two complex procedures in European environmental law.

35. The case stems from a Commission authorisation decision under Article 60 of the REACH Regulation. It is based on an *application for authorisation* made by three companies. By the *authorisation decision*, the Commission permits them to use a certain substance, DEHP, a 'plasticiser', for precisely defined purposes. Any use without such authorisation is prohibited as the substance has reproductive toxicity properties. The Commission nevertheless authorises the uses applied for because, in its view, socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance.

36. It should be noted that the application for authorisation did not seek an authorisation on that basis, that is to say, a balancing exercise pursuant to Article 60(4) of the REACH Regulation, but an authorisation on the ground that the reproductive toxicity risks of DEHP are adequately controlled in

accordance with Article 60(2). The examination of the application concluded, however, that the application did not demonstrate such control.

37. ClientEarth objects to the authorisation on the basis of the Aarhus Regulation. To that end, it first made a *request for review* to the Commission, as provided for in Article 10 of that regulation, in which it complained of alleged deficiencies in the authorisation decision. Some of those complaints are linked to shortcomings in the application for authorisation, as it did not seek a balancing exercise and that the application for authorisation did not demonstrate that the risk is adequately controlled. Furthermore, ClientEarth objects to aspects of the balancing exercise on the basis of which the Commission justified the authorisation.

38. The conditions governing the admissibility of the request for review under Articles 10 and 11 of the Aarhus Regulation are not disputed.

39. By the contested *review decision*, the Commission nevertheless rejected the request for review. ClientEarth brought an action to challenge that decision, which was dismissed by the General Court in the judgment under appeal.

40. These two successive procedures characterise the present appeal. I will first address ClientEarth's interest in bringing proceedings (see A) and then examine the sixth ground of appeal, which concerns the failure to take into account other risks of substances in the balancing exercise (see B). This leads to my proposal that the judgment under appeal should be set aside and the contested review decision should be annulled.

41. It is therefore possible, strictly speaking, to rule on the appeal without considering the other grounds of appeal. It should be borne in mind, however, that the Court has thus far ruled only once on an appeal relating to the review procedure, (11) which did not clarify many of the questions raised. A finding that the General Court made further errors in law is therefore important for future cases, even though they would not lead to the judgment under appeal being set aside (see C).

A. Interest in bringing proceedings

42. ClientEarth's interest in bringing proceedings would be questionable if the authorisation decision has now lost its effect by the passage of time or because the Commission had revoked it. In that case, it would be doubtful that ClientEarth could procure an advantage from the present appeal. (12)

43. Article 2 of the authorisation decision provided for a review period until 21 February 2019. As the Commission has not issued any new authorisation since then, it seems conceivable that the authorisation has expired.

44. The parties agree, however, that the authorisation decision is valid for at least one of the authorisation applicants under Article 61(1) of the REACH Regulation because it submitted a review report, on which the Commission must still decide, within that period.

45. Because the authorisation decision is thus still valid, the success of the appeal and of the underlying action could ultimately lead to the decision being annulled and ClientEarth thereby procuring the advantage sought.

46. Consequently, ClientEarth still has the necessary interest in bringing proceedings.

B. Sixth ground of appeal: taking into account other risks of the substance in the balancing exercise

1. Examination of the appeal

47. By the sixth ground of appeal, ClientEarth contests the General Court's findings as to which risks of the substance are to be taken into account in the balancing exercise under Article 60(4) of the REACH

Regulation.

48. The background to this ground of appeal is the fact that DEHP has thus far required authorisation only on account of reproductive toxicity properties within the meaning of Article 57(c) of the REACH Regulation. In addition, ECHA and the Commission have, however, also included DEHP in the candidate list, as a substance of very high concern, on account of its endocrine disrupting properties within the meaning of Article 57(f), that is, its hormonal effects, in accordance with Article 59, although there is not yet an authorisation requirement on that basis. (13)

49. Although those endocrine disrupting properties of DEHP were already known at the time of the authorisation decision, the General Court accepted, in the contested paragraph 289 of the judgment under appeal, that the ECHA Committees for Risk Assessment and for Socio-economic Analysis and the Commission took into account only the reproductive toxicity properties of DEHP in the balancing exercise referred to in Article 60(4).

50. It must therefore be clarified what risks of a substance are to be taken into account in a balancing exercise under Article 60(4) of the REACH Regulation.

51. According to the wording of that provision in, for example, the German, French, Danish, Spanish and Italian versions, a use may be authorised if socio-economic benefits outweigh the *risks* to human health or the environment arising from the use of the substance. The wording of that ground for authorisation thus differs from Article 60(2) of the REACH Regulation, which expressly refers to only one *risk* [singular in the German version], namely the risk justifying the authorisation requirement. In those versions, the wording of Article 60(4) therefore suggests, in comparison with the other ground for authorisation, that all risks of the substance should be taken fully into account in the balancing exercise. However, in other versions such as the English, Dutch or Portuguese versions, paragraph 4 also only refers to the risk. Those versions may likewise be interpreted as meaning that all risks should be taken fully into account, although that conclusion is not quite as stringent as for the versions referred to above.

52. The General Court nevertheless relies, in paragraphs 218 to 223 of the judgment under appeal, on the link between the two grounds for authorisation under Article 60(2) and (4) of the REACH Regulation and on the distinction between the candidate list and the justification for an authorisation requirement in order to restrict the balancing exercise to the risks justifying the authorisation requirement.

53. The General Court correctly holds that an authorisation on the ground that the risk is adequately controlled under Article 60(2) of the REACH Regulation relates solely to the risk on which the authorisation requirement is based. An authorisation applicant is obliged to submit information regarding only that risk pursuant to Article 62(4)(d). If it is able to demonstrate that that risk is adequately controlled, authorisation is not precluded by other risks, even if the substance is already included in the candidate list on account of those risks. Inclusion of a substance in the candidate list is just one step in a process which may in future lead to an authorisation requirement, but does not necessarily do so.

54. Therefore, the primary function of the balancing exercise under Article 60(4) of the REACH Regulation is similarly to overcome the risk justifying the authorisation requirement. Without that risk there would be no authorisation requirement.

55. However, the General Court and the Commission fail to recognise that socio-economic benefits of a use depend not only on the advantages of the use, but also on its other risks to the environment and health, as those risks are likewise socio-economic factors. If they result in damage to the environment or health, they represent a burden on society and give rise to economic costs. The risks therefore *diminish* socio-economic benefits and, accordingly, must be taken into account in assessing whether benefits outweigh the risk justifying the authorisation requirement.

56. This is particularly evident in the analysis of alternatives that is also necessary for an authorisation pursuant to Article 60(4) of the REACH Regulation. Under Article 60(5), the Commission must take into

account ‘all relevant aspects’, including, under point a, the ‘overall risks to human health and the environment’. Those overall risks necessarily include all conceivable risks of the alternative and of the use applied for. Neither can reference be made to an alternative that does not entail the risk justifying the authorisation requirement but other even more serious risks, nor is it reasonable to take into account such other risks only for alternatives but not for the authorisation applied for. This would not give the comparison of the overall risks which is required as the basis for an analysis of alternatives.

57. In the case at issue, the Committee for Socio-economic Analysis also expressly took into account other risks of alternatives, describing the avoidance of disposal of PVC waste containing DEHP in landfill or by incineration as a socio-economic benefit of the authorisation applied for. (14)

58. The balancing exercise would therefore be incomplete if the advantages of a use were taken fully into account but, in the case of the disadvantages, only the risk justifying the authorisation requirement.

59. Before the General Court, the Commission also referred to its Explanatory Memorandum to the Proposal for the REACH Regulation, where it had similarly stated that effects other than those justifying the authorisation requirement would not be taken into account. Such effects could be addressed through restrictions. The Commission justified this by the efficiency of the process. (15)

60. Considerations of efficiency may permit low, remote or hypothetical risks to be disregarded in the balancing exercise. In particular, it may be permissible to disregard as negligible risks that are demonstrated to be adequately controlled by restrictions. Such limitation is consistent with the discretion available to the Commission in finding the basic facts for the assessment of complex scientific situations and balancing exercises. (16) However, risks on the basis of which, as being *of very high concern*, a substance has already been included in the candidate list under Article 59 of the REACH Regulation necessarily form part of the relevant facts of the individual case which must be examined, carefully and impartially, by the Commission in the exercise of its discretion. (17)

61. Furthermore, it is consistent with the precautionary principle, on which the REACH Regulation is founded according to recital 9 and Article 1(3), that the relevant risks of a use to health and the environment are fully taken into account. Recital 69 emphasises that authorisations in particular are subject to that principle.

62. The correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the use of the contested active substances and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research. (18) The same considerations apply to environmental risks. (19)

63. Lastly, as ClientEarth rightly asserts, a comprehensive balancing exercise of this nature also comes much closer to the aim of ensuring a high level of protection (20) than a balancing exercise in which certain risks are ignored.

64. Nor is that conclusion precluded by the fact that the General Court has already ruled that the inclusion of a substance in the candidate list on grounds of additional risks does not establish an obligation to supplement a pending application for authorisation in the light of those risks. Such inclusion has no impact on the authorisation procedure. (21)

65. In this regard, it should be noted, first, that the Court of Justice did not address that point in its judgment on the appeal against that earlier judgment of the General Court. (22) The Court of Justice has not yet therefore ruled on that point.

66. Second, a distinction must be drawn between inclusion of a substance in the candidate list and the risks arising from the use of that substance. From a strictly formal point of view, inclusion has no direct effect on a pending authorisation procedure. However, this does not mean that the risks giving rise to

inclusion should not be taken into account in the socio-economic balancing exercise in the same way as all other relevant risks. In this connection, inclusion in the candidate list is of interest only in so far as it confirms the risks and their significance.

67. Lastly, the principle of legal certainty, on which the Commission relied in the contested review decision and which it mentions in passing in the response, does not lead to another conclusion. In the review decision, the Commission explained that that principle does not allow endocrine disrupting properties to be taken into account, as those properties had only been established a year after the application for authorisation. The authorisation applicant could not therefore be expected to take those risks into account in its application. (23)

68. According to settled case-law, however, the legality of a Commission decision is to be assessed in the light of the information available to the Commission when the decision was adopted. (24) Even if an authorisation applicant was not yet able to take into account certain information relevant to the decision, the Commission may not therefore ignore that information if it receives it before the decision. In the case of the authorisation decision and a fortiori in the case of the contested review decision, the report by Denmark on the endocrine disrupting properties of DEHP was already available to the Commission and ECHA had already recognised the associated risks to the environment by placing DEHP in the candidate list. (25)

69. Consequently, the judgment under appeal is vitiated by an error in law because it permits the endocrine disrupting properties of DEHP not to be taken into account in the balancing exercise under Article 60(4) of the REACH Regulation. That error forms the basis for the rejection of the form of order sought, with the result that the judgment in its entirety must be set aside.

2. Examination of the action before the General Court

70. In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, the Court of Justice may, where the decision of the General Court has been set aside, either itself give final judgment in the matter, where the state of the proceedings so permits, or refer the case back to the General Court.

71. In view of the failure to take into account other risks of DEHP, the state of the proceedings does permit final judgment to be given. The Commission should have taken into account the endocrine disrupting properties of DEHP in the contested review decision. Because it did not do so, that decision must also be annulled in its entirety.

72. It should also be noted that, although the authorisation decision is likewise vitiated by that deficiency, it would not be directly affected by the annulment of the review decision. It is true that in the decision on the request for review the Commission should take into consideration that the authorisation is based on an incomplete balancing exercise. It cannot be ruled out, however, that the Commission instead grants a new authorisation pursuant to Article 60(2) of the REACH Regulation on the basis of the review report submitted by the remaining authorisation applicant, (26) with the result that the request for review made by ClientEarth would become devoid of purpose. The ECHA Committees for Risk Assessment and for Socio-economic Analysis have already concluded that the new information demonstrates that the reproductive toxicity risks are adequately controlled. (27)

C. The other grounds of appeal

73. The other grounds of appeal relate to the admissibility of submissions in an action concerning a request for review, the requirements governing an application for authorisation, the standard of evidence to be satisfied by such an action, the analysis of alternatives, the chemical safety report and the precautionary principle.

1. First ground of appeal: admissibility of pleas and arguments

74. The first ground of appeal concerns the General Court's findings on the scope of an action brought against the rejection of a request for review under the Aarhus Regulation. ClientEarth objects, first, to the finding that the action can concern only the contested review decision and not the application for authorisation (see (a)) and, second, to the fact that the General Court limited its submissions to pleas and arguments which it had presented in its request for review (see (b)).

(a) First part of the first ground of appeal: subject matter of the action brought against the contested review decision

75. By the first part of the first ground of appeal, ClientEarth objects to the delimitation by the General Court of the subject matter of an action brought pursuant to Article 12 of the Aarhus Regulation. It must be clarified whether, by its action, ClientEarth may also complain of deficiencies in the application for authorisation which led to the Commission authorisation decision under review.

76. The General Court rightly pointed out in paragraph 53 of the judgment under appeal that the action brought by the review applicant can concern only the legality of the contested review decision. As regards deficiencies in the application for authorisation, in paragraph 54 it takes the view that these could be criticised by ClientEarth only in so far as the Commission endorsed those deficiencies in the review decision.

77. It is therefore crucial whether and, as the case may be, to what extent an NGO may make deficiencies in an application for authorisation the subject matter of a review procedure.

78. It should be recalled that, under Article 10(1) of the Aarhus Regulation, certain NGOs are entitled to submit a reasoned request and trigger an internal review of an administrative act by the EU institution that has adopted it under environmental law. The request for review relates, pursuant to that provision, to the reassessment of that act, (28) in this case the authorisation decision.

79. The Court has ruled that a request for internal review of an administrative act is thus intended to establish that, as alleged, the act in question is unlawful or (in particular) that it is not well founded. (29) The NGO may then, in accordance with Article 12 of the Aarhus Regulation, read in conjunction with Article 10 thereof, bring the matter before the EU judicature. It may institute proceedings against the decision rejecting the request for internal review as unfounded. It may rely on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers. (30)

80. In this connection, however, the infringement of an essential procedural requirement relates to rules applying to the review procedure. There is no indication of the extent to which complaints may be raised in the request for review against formal and procedural deficiencies in the authorisation procedure.

81. Article 9(3) of the Aarhus Convention requires only the possibility of a challenge on grounds of contravention of provisions relating to the environment. This wording is narrower than Article 9(2), which permits a challenge of substantive and procedural legality.

82. Because Articles 10 to 12 of the Aarhus Regulation transpose only Article 9(3) of the Convention, those rules are intended to permit solely complaints relating to the contravention of provisions relating to the environment and not a comprehensive challenge of the substantive and procedural legality of an act.

83. In so far as the application for authorisation must specify the use (Article 62(4)(c) of the REACH Regulation) and include a chemical safety report (Article 62(4)(d)) and an analysis of alternatives (Article 62(4)(e)), these are provisions relating to the environment. That information is intended in particular to highlight the environmental risks of the use applied for and of its alternatives.

84. Furthermore, the information is also important for the participation of third parties in the authorisation procedure. Under Article 64(2) of the REACH Regulation, ECHA must make available

broad information on uses for which applications have been received. In addition, it must set a deadline by which information on alternative substances or technologies may be submitted by interested third parties. Article 60(4)(c), the fourth sentence of Article 64(3), Article 64(4)(b) and recital 81 also provide for the consideration of information submitted by third parties. ClientEarth explains that it has participated in authorisation procedures in this manner.

85. As the General Court itself acknowledges in paragraph 103 et seq. of the judgment under appeal, moreover, an authorisation under Article 60(7) of the REACH Regulation is permitted only if the application satisfies the conditions laid down in Article 62. These include the safety report and the analysis of alternatives.

86. If an authorisation could not be granted because the application did not satisfy Article 62(4)(d) and (e) of the REACH Regulation, NGOs must therefore be able to challenge such deficiencies in a review and the subsequent action. On the other hand, the admissibility of such submissions in the review procedure cannot be influenced by whether the Commission expressly endorses the deficiency.

87. Consequently, ClientEarth is to some extent right to object to paragraphs 234 to 236 of the judgment under appeal. In that passage, the General Court rejected as inadmissible the argument that the analysis of alternatives proposed in the application for authorisation was deficient since that application did not specify the function of DEHP. In the Court's view, irrespective of what the applicants for the authorisation did or did not indicate in the application for authorisation, the Commission expressly identified a function of DEHP for the purposes of the authorisation. It follows from the above considerations that this finding of inadmissibility is vitiated by an error in law.

88. However, the General Court explains convincingly in reasoning in the alternative in paragraphs 63 to 70 of the judgment under appeal, which are not contested by ClientEarth, that the indication of use does not depend on a specific function being ascribed to the substance in question.

89. Accordingly, ClientEarth's submission regarding the failure to specify a function of DEHP in the application for authorisation was in any event unfounded and the error in law made by the General Court in assessing the admissibility of that submission does not therefore call the judgment into question.

(b) Second part of the first ground of appeal: subject matter of the review procedure

90. By the second part of the first ground of appeal, ClientEarth objects to the finding made in paragraph 55 of the judgment under appeal that in an action for annulment of a review decision only the pleas and arguments already presented by the applicant in the request for review are admissible.

91. On a superficial reading, the Court of Justice has recently given a very similar ruling on this point in *TestBioTech*. It held that proceedings brought against the rejection of a request for review cannot be founded on new grounds or on evidence not appearing in the request for review. Otherwise the requirement, in Article 10(1) of the Aarhus Regulation, relating to the statement of grounds for such a request would be made redundant and the object of the procedure initiated by the request would be altered. (31)

92. This finding by the Court of Justice is consistent with its other case-law concerning the subject matter of proceedings. The subject matter of proceedings for failure to fulfil obligations under the Treaty is delimited by the letter of formal notice and the reasoned opinion, (32) just as the subject matter of trade mark proceedings is determined by the claims made to EUIPO and the evidence submitted there. (33) The subject matter of the proceedings before the General Court also may not be changed in the appeal. (34) As has already been stated, moreover, the legality of a Commission decision is to be assessed in the light of the information available to the Commission when the decision was adopted, (35) in particular the content of an application to be decided by it.

93. The Court has also interpreted Article 9(3) of the Aarhus Convention, which is transposed by the Aarhus Regulation, in this manner. That provision does not preclude a rule imposing a time limit which requires objections regarding compliance with the relevant rules of environmental law to be submitted from the administrative procedure stage. Such a rule may allow areas for dispute to be identified as quickly as possible and, where possible, resolved during the administrative procedure so that judicial proceedings are no longer necessary. Thus, such a rule imposing a time limit may contribute to the objective of Article 9(3) of the Convention of providing effective judicial mechanisms and appears also to be in line with Article 9(4), which requires that the procedures referred to, inter alia, in Article 9(3) provide 'adequate and effective' remedies that are 'equitable'. (36)

94. ClientEarth expressly concurs with the finding in *TestBioTech* in the response. However, it rightly relies on the abovementioned case-law on the delimitation of the subject matter of the proceedings, according to which, first, new *arguments* connected with already submitted grounds in the application are admissible (37) and, second, it must be possible to *respond* to the statement of grounds in a decision rejecting an application. (38)

95. Both categories of new submissions are consistent with the objective set out in recital 19 of the Aarhus Regulation and Article 9(4) of the Aarhus Convention of ensuring adequate and effective remedies. That objective also follows from Article 47 of the Charter of Fundamental Rights.

96. By contrast, the General Court's finding in paragraph 55 of the judgment under appeal is too restrictive because in that paragraph the General Court not only declares – rightly – new pleas to be inadmissible, but also – erroneously – new arguments in general.

97. However, in order to call the judgment into question, the application of that finding to ClientEarth's submissions would also have to constitute an error in law.

98. In this regard, ClientEarth stresses the rejection of submissions regarding the concept of use, the use of waste and the quantification of socio-economic benefits.

(i) Concept of use

99. In paragraphs 61 and 62 of the judgment under appeal, the General Court rejects as inadmissible ClientEarth's argument that the concept of 'use' consists of an 'active' deployment or introduction of a certain substance into an 'industrial process'. In the Court's view, that argument was not included sufficiently clearly in the request for review, with the result that it could not have been evident to the Commission.

100. It is nevertheless undisputed that the request for review related to the question whether the application for authorisation specified the desired uses of DEHP sufficiently clearly. In paragraph 61 of the judgment under appeal, the General Court even refers to ClientEarth's submission in the request for review that a use of DEHP requires that substance to be used 'in a preparation' or incorporated 'in an article'. In addition, in paragraph 71 of the judgment under appeal, the General Court mentions the Commission's reasons for rejecting that submission in the contested review decision.

101. If in the action ClientEarth insists on the 'active' deployment of a certain substance into an 'industrial process', this should be seen, for the purposes of the present case at least, merely as a further development of the objection raised in the request for review. It is still a matter of whether the application for authorisation and the authorisation concern uses of DEHP within the meaning of the REACH Regulation.

102. The General Court's finding regarding the inadmissibility of this submission by ClientEarth is therefore vitiated by an error in law.

103. The error in law has effect, however, only if the rejection, in the alternative, of that submission as unfounded in paragraphs 63 to 92 of the judgment under appeal also constitutes an error in law. It will be

shown in the discussion of the third ground of appeal that this is not the case (see 4 below, in particular points 143 and 144).

(ii) Arguments relating to the use of waste

104. ClientEarth also objects that, in paragraphs 74, 75, 85 and 87 of the judgment under appeal, the General Court rejects as inadmissible various arguments based on the fact that the Commission authorised the use of material obtained from waste. The Commission authorised a recycling process that infringes waste law and incorrectly determined end-of-waste status.

105. The question whether these arguments actually fall outside the subject matter of the proceedings can be left open as, in substance, they are unfounded because, under Article 2(2), the REACH Regulation does not apply to waste. The authorisation decision cannot therefore regulate those matters of waste law and expressly does not regulate them, according to recital 8 of that decision. Instead, the decision requires that processed PVC waste has already ceased to be waste before authorised use.

106. In the absence of EU rules relating to end-of-waste status of PVC waste containing DEHP, on the other hand, the decision rests with the Member States, (39) which are subject to strict requirements with a view to prevention of any adverse impact on the environment and human health. (40) Any infringement of waste law thus falls within the responsibility of the Member State, which determines end-of-waste status.

107. This part of the first ground of appeal is therefore ineffective.

(iii) Socio-economic benefits – quantification of the risk

108. Lastly, ClientEarth challenges paragraph 197 of the judgment under appeal, in which the General Court rejects as inadmissible the argument that the absence of quantification of the risk to workers' health calls into question the socio-economic balancing exercise.

109. While the request for review did criticise the socio-economic balancing exercise, the absence of quantification of the risk to workers' health was not actually mentioned. Nor is it evident which criticism raised in the application that argument was intended to develop. In so far as complaints were raised regarding the consideration of certain risks, they did not relate to their quantification, but to the fact that they were not included in the balancing exercise at all (see B, point 51 et seq., above).

110. The General Court was therefore right to consider this objection to be inadmissible and this part of the first ground of appeal is thus unfounded.

2. Fourth ground of appeal: requirements governing the application for authorisation

111. As the request for review of an authorisation can also be made on the ground that the authorisation was based on deficient information in the application for authorisation, (41) the requirements governing the content of that application are relevant. They are the subject of the fourth ground of appeal.

112. As has already been stated, an authorisation under Article 60(7) of the REACH Regulation is granted only if the application satisfies the requirements laid down in Article 62. (42) Article 62(4) describes the information which the application must include, in particular a chemical safety report (point d) and an analysis of the alternatives (point e). The chemical safety report must meet the requirements set out in Annex I and, in particular, cover the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV. The analysis of the alternatives must consider their risks and the technical and economic feasibility of substitution, including, if appropriate, information about any relevant research and development activities by the applicant.

113. The parties and the General Court consider that the verification of those requirements governing the application for authorisation should be distinguished from the assessment of the conditions for

authorisation under Article 60(2) and (4) of the REACH Regulation. ClientEarth nevertheless objects that, in paragraph 109 of the judgment under appeal, the General Court does not oblige the Commission, in the context of the chemical safety report, to examine the substance of the elements to be submitted with the application on the basis of Article 60(7) read in conjunction with Article 62 and Annex I.

114. The General Court's finding is based on the view that the wording of the provisions in question does not establish any such obligation for the Commission.

115. However, this finding is not correct.

116. It is true that there is no rule obliging the *Commission* to examine the substance of the information submitted. However, the first sentence of Article 64(3) of the REACH Regulation expressly states that the *ECHA Committees* for Risk Assessment and for Socio-economic Analysis must begin their assessment of the application by checking whether the application includes all the information specified in Article 62 that is relevant to their remits. The second sentence provides that they must request further information from the authorisation applicant, if that is necessary.

117. The Committees can accomplish that task only if they examine the substance of the information submitted with the application. In doing so, they must anticipate the assessment of the conditions governing authorisation under Article 60(2) or (4). Nevertheless, there are two steps, as the Committees must also take into account, in their opinions on authorisation, their own expertise and information not submitted by the authorisation applicants, but by third parties pursuant to the third and fourth sentences of Article 64(3) in particular.

118. The Committees are independent in their judgement in accordance with Article 85(7), Article 88 and recital 95 of the REACH Regulation. However, the Commission takes their opinions into account where it authorises a use pursuant to Article 60(2) or (4) of the REACH Regulation. Should the Committees establish that the information submitted is deficient, the Commission may authorise the use of the substance applied for only if, at the same time, it demonstrates why the Committees' assessment is incorrect. The Commission thus either endorses the Committees' findings regarding the completeness of the information submitted or itself examines the substance of the information.

119. The General Court's finding in paragraph 109 of the judgment under appeal that the Commission is not obliged to examine the substance of the chemical safety report to be submitted with the application on the basis of Article 60(7) read in conjunction with Article 62 and Annex I thus misunderstands the procedure laid down in Articles 60, 62 and 64 of the REACH Regulation and, consequently, is vitiated by an error in law.

120. However, that error in law in the judgment under appeal calls the judgment into question only if it corresponds to a deficiency in the contested review decision. A significant omission in the application dossier must become apparent in the authorisation decision at the latest. The analysis of the fifth ground of appeal will nevertheless show that this is not the case with regard to the chemical safety report in this instance (see 5 below, in particular point 154).

3. Second ground of appeal: standard of evidence for authorisation applicants in the review procedure

121. By the second ground of appeal, ClientEarth objects to the standard of evidence established by the General Court for the review procedure.

122. The Court has already ruled that a party requesting the internal review of an administrative act under environmental law is required to put forward the facts or legal arguments of sufficient substance to give rise to serious doubts as to the assessment made in that act by the EU institution or body. (43) ClientEarth invokes that standard in connection with this ground of appeal.

123. Although the General Court also invokes that standard of evidence in paragraph 57 of the judgment under appeal, ClientEarth objects to its application to complaints regarding the chemical safety report submitted with the application for authorisation and the analysis of alternatives by the Committee for Socio-economic Analysis.

(a) First part of the second ground of appeal: the chemical safety report in the application for authorisation

124. By the first part of the second ground of appeal, ClientEarth challenges the rejection of objections to the chemical safety report submitted with the application for authorisation. It argues that the standard of evidence applied to its submissions is disproportionate.

125. In paragraph 112 of the judgment under appeal, the General Court finds that ClientEarth failed to provide evidence that would allow a conclusion to be reached that the chemical safety report submitted with the application for authorisation did not comply with the requirements of Article 60(7), Article 62(4)(d) and Annex I of the REACH Regulation.

126. However, the General Court did not base that finding on an appraisal of evidence or a certain standard of evidence, but on the view that the completeness of the application for authorisation should not be examined in substance but only in form, as can be seen in particular from paragraph 113 of the judgment under appeal. That objection to the standard of evidence therefore rests on a misunderstanding of the judgment under appeal.

127. The same holds for the objections to paragraphs 148 to 150 of the judgment under appeal, where the General Court found that ClientEarth should have specifically challenged the assessment of the Committee for Socio-economic Analysis in order to invoke deficiencies in the chemical safety report. On this point too, the General Court again relies, implicitly at least, on its finding that the requirements governing the quality of the application for authorisation are only formal in nature. In so far as it requires specific objections, it is referring to the assessments by the Commission or the Committee forming the basis for the authorisation decision, which can subsequently be contested only in substance.

128. Because they rest on a misunderstanding of the judgment under appeal, those complaints against the required standard of evidence are unfounded.

129. The considerations relating to the fourth ground of appeal have shown that the General Court's reasoning concerning the verification of the content of the application is vitiated by an error in law (see 2 above, in particular point 115 et seq.). The examination of the fifth ground of appeal will show, however, that the assessment of the chemical safety report by the Committees and the Commission in the authorisation decision gives no cause for complaint (see 5 below, in particular point 154), with the result that that error in law does not lead to the judgment under appeal being set aside.

(b) Second part of the second ground of appeal: analysis of alternatives

130. The second part of the second ground of appeal concerns the analysis of alternatives by the Committee for Socio-economic Analysis. ClientEarth objects in this regard that the General Court held, in paragraph 248 of the judgment under appeal, that it should have provided evidence that would render the factual assessments implausible as regards the lack of alternatives. The General Court thus seems to expect, in the context of the request for review, a full analysis of alternatives in lieu of demanding this of the application for authorisation. This effectively means that the request for review would have to prove that the reviewed decision is unlawful.

131. With that argument, however, ClientEarth misunderstands the standard of review applied by the EU judicature in respect of substantive objections where the authorities of the European Union assess complex scientific and technical matters in order to determine the nature and scope of the measures which they adopt. Those authorities have a broad discretion, which limits review by the European Union judicature to

verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the European Union judicature cannot substitute its assessment of scientific and technical facts for that of the institutions on which alone the FEU Treaty has placed that task. (44)

132. Substantive objections to such an assessment by the authorities of the European Union must therefore demonstrate a manifest error, a misuse of powers or discretion being manifestly exceeded.

133. Contrary to the view taken by ClientEarth, the fact that in one judgment cited by the General Court (45) the submissions fell very clearly short of the necessary standard of evidence for a manifest error of appraisal does not mean that lower requirements apply in other cases.

134. However, that standard does not necessarily require that the substance of the assessment by the authorities of the European Union must be definitively refuted. Rather, even in the case of complex decisions, the courts of the European Union must examine whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a misuse of powers. (46) In particular, where a party claims that the institution competent in the matter has committed a manifest error of appraisal, the courts of the European Union must verify whether that institution has examined, carefully and impartially, all the relevant facts of the individual case, facts which support the conclusions reached. (47)

135. Although the broad discretion also applies to some degree to the finding of the basic facts, (48) it is sufficient to demonstrate that manifestly relevant factors were not taken into account in the assessment. The request for review can thus justify serious doubts as to the assessment carried out since, despite the broad discretion enjoyed by the authorities of the European Union, they must at least show that they were aware of those doubts and why they nevertheless arrived at their assessment.

136. For precisely this reason, however, the references made by ClientEarth to doubts considered by the Committees in connection with the assessment cannot prove a manifest error of assessment. On the contrary, those considerations show that the authorities of the European Union took those factors into account in the exercise of their discretion.

137. In so far as, by that complaint, ClientEarth implicitly objects that the Commission accepted as adequate the information in the application for authorisation regarding the analysis of alternatives, without the General Court finding fault with this, the conclusion concerning the fourth ground of appeal also holds. In principle, a substantive examination of the completeness of the application for authorisation is required (see 2 above, in particular point 115 et seq.). However, the examination of the third ground of appeal will show that the analysis of alternatives in the authorisation decision gives no cause for complaint (see 4, immediately below). Therefore, any error in law made by the General Court in assessing the examination of the application for authorisation in respect of the analysis of alternatives is not relevant to the decision.

4. Third ground of appeal: alternatives to the use applied for

138. By the third ground of appeal, ClientEarth challenges the assessment of its objections regarding the analysis of alternatives in the authorisation decision.

139. The first sentence of Article 60(4) of the REACH Regulation provides that an authorisation may be granted, where socio-economic benefits outweigh the risk, if there are no suitable alternative substances or technologies. According to the second sentence, in that decision inter alia the analysis of the alternatives submitted by the applicant under Article 62(4)(e) and any information on alternative substances or technologies submitted by interested third parties under Article 64(2) are to be taken into consideration.

140. That provision cannot be interpreted as meaning that any alternative substance or any alternative technology precludes authorisation because, according to the first sentence of Article 55 of the REACH Regulation, substances subject to authorisation are to be replaced only by suitable alternative substances or

technologies, where these are economically and technically viable. The second sentence states that the analysis of alternatives in the authorisation procedure is carried out to this end.

141. The General Court consistently acknowledged, for example in paragraphs 71, 91, 238, 242 and 243 of the judgment under appeal, that the authorisation was granted for DEHP in its capacity as plasticiser in the PVC recyclate placed on the market after PVC lost its waste status. In addition, in paragraph 91, it found that it is not incorrect to consider as possible alternatives other mixtures which do not at all contain the substance or other processes in which the function provided by the substance can be met by other means.

142. ClientEarth contends that the function of DEHP of increasing the flexibility and elasticity of PVC is relevant to the analysis of alternatives. The aim of the authorisation procedure is to reduce and, in the long term, replace the use of the substance concerned, in this case DEHP. Even if safe alternative plasticisers existed, the processing of DEHP could be authorised, according to the logic employed by the General Court, as long as PVC waste containing DEHP occurred. In fact, alternative plasticisers or alternatives to such PVC containing DEHP should, however, have been investigated.

143. These considerations are unconvincing, however. The assessment of alternative substances and technologies relates to the specific use for which an authorisation is sought. The concept of 'use' is defined extremely broadly in Article 3(24) of the REACH Regulation as 'processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation'.

144. According to the authorisation at issue, DEHP is not intended to be used abstractly in the production of PVC but by recycling companies as an element of PVC recyclate. It is of secondary interest to those companies whether other suitable plasticisers for PVC exist. The crucial factor is whether they can be referred to other kinds of recyclate, whether PVC recyclate without DEHP or recyclate from other plastics.

145. This ground of appeal is therefore unfounded.

146. It should be noted, however, that although the substitutability of DEHP is not important for the analysis of alternatives in this case, it may be a valid factor as part of the comprehensive socio-economic balancing exercise. If DEHP can be substituted favourably by less hazardous substances, the advantages arising from the use of PVC recyclate containing DEHP are less than if that is not the case. At the same time, PVC recyclate containing DEHP is likely to be less available, as the marketing of new PVC containing DEHP will be less attractive (49) or will even be prevented by restrictions under Article 67 of the REACH Regulation. (50) Lastly, demand for PVC recyclate containing DEHP is also likely to fall or even disappear entirely. Those considerations do not fall within the scope of the appeal, however.

5. Fifth ground of appeal: the chemical safety report in the balancing exercise

147. The fifth ground of appeal concerns the question whether the balancing exercise under Article 60(4) of the REACH Regulation could be carried out on the basis of the chemical safety report submitted.

148. As has been mentioned, Article 60 of the REACH Regulation envisages two bases for an authorisation. Under paragraph 2, it may be granted if the risk to human health or the environment is adequately controlled. That provision requires in particular that the chemical safety report documents such control. If, on the other hand, it is not ensured that the risk is adequately controlled, paragraph 4 permits the authorisation 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.

149. In the present case, the Commission concurs with the Committee for Risk Assessment that the application for authorisation does not demonstrate that the risk to workers who process PVC recyclate containing DEHP is adequately controlled. (51) An authorisation under Article 60(2) of the REACH Regulation was not therefore an option.

150. Rather, the Commission granted the authorisation on the basis of the balancing exercise under Article 60(4) of the REACH Regulation.

151. ClientEarth maintains, however, that such a balancing exercise was not possible on account of deficiencies in the chemical safety report.

152. It challenges, first, the General Court's finding in paragraph 132 of the judgment under appeal that that objection could have an impact only on the authorisation under Article 60(2) of the REACH Regulation and not on the authorisation under Article 60(4). Second, it complains about the findings in paragraphs 135 and 136 that the information submitted was in any case adequate for the balancing exercise.

153. ClientEarth is correct in its assertion that deficiencies in the chemical safety report may preclude the application of Article 60(4) of the REACH Regulation. In order to establish that socio-economic benefits of a use outweigh the risk, that risk must be identified with sufficient precision. This is underlined by Article 60(4)(a), which provides that the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed, must be taken into consideration. Should the application of Article 60(2) already be excluded on the ground that that risk is not adequately described, this could also preclude an authorisation on the basis of benefits outweighing risk.

154. If the General Court's finding in paragraph 132 of the judgment under appeal were to preclude that objection, it would be vitiated by an error in law. The findings in paragraphs 135 and 136 suggest, however, that, in paragraph 132, the General Court did not intend to make such a broad statement. At least, as reasoning in the alternative, they would be capable of maintaining the judgment on this point. In paragraphs 135 and 136, the General Court argues convincingly that the data presented by the authorisation applicant at least permitted sufficient conclusions to be drawn as to the risk to workers in order to carry out the balancing exercise.

155. In so far as ClientEarth objects that the risk assessment does not specifically concern the authorised use, it misunderstands paragraph 135 of the judgment under appeal in particular. That paragraph states that, while the information provided is not specific to that use, this does not mean that no conclusions regarding the risk of use can be drawn from that information.

156. The question whether that factual assessment of the data is correct is a matter of appraisal of evidence falling outside the scope of the review in appeal proceedings.

157. The fifth ground of appeal is therefore unfounded.

6. Seventh ground of appeal: precautionary principle

158. The seventh ground of appeal concerns the precautionary principle. Although ClientEarth criticises statements made in paragraphs 284 and 295 of the judgment under appeal, its argument that the precautionary principle should be taken into consideration is not contrary to those statements or the judgment as a whole.

159. In so far as ClientEarth maintains in particular that the General Court found that in applying Article 60(4) of the REACH Regulation the Commission is exempt from the application of the precautionary principle, it misunderstands the judgment. Rather, in paragraphs 290 to 294 of the judgment under appeal, the General Court explains that that provision constitutes the interaction between the precautionary principle and the principle of proportionality.

160. Accordingly, this ground of appeal is unfounded.

D. Conclusion of the legal assessment

161. In summary, the judgment under appeal should be set aside and the contested review decision should be annulled because they accepted that the endocrine disrupting properties of DEHP were not taken into account in the socio-economic balancing exercise in the authorisation decision. The General Court's findings regarding the admissibility of complaints as to the application for authorisation, regarding the review of the content of the application, and also regarding the inadmissibility of new arguments, are likewise vitiated by errors in law, but do not ultimately lead to the judgment under appeal being set aside.

VI. Costs

162. Under Article 184(2) of its Rules of Procedure, where the appeal is well founded and the Court of Justice itself gives final judgment in the case, the Court is to make a decision as to the costs.

163. Under Article 138(1) of the Rules of Procedure, which applies *mutatis mutandis* to appeal proceedings pursuant to Article 184(1) of those rules, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

164. Furthermore, under Article 184(4) of the Rules of Procedure, where the appeal has not been brought by an intervener at first instance, he may not be ordered to pay costs in the appeal proceedings unless he participated in the written or oral part of the proceedings before the Court of Justice. In that case, the Court may decide that he shall bear his own costs. This applies to the costs incurred by ECHA in the appeal proceedings.

165. As regards the costs incurred by ECHA before the General Court, the grounds set out in paragraph 310 of the judgment under appeal still apply.

166. Consequently, the Commission must pay the costs incurred by ClientEarth and bear its own costs. ECHA, on the other hand, must bear its own costs in both instances.

VII. Conclusion

167. I therefore propose that the Court should:

(1) Set aside the judgment of the General Court of the European Union of 4 April 2019, *ClientEarth* v *Commission* (T-108/17, EU:T:2019:215);

(2) Annul Decision C(2016) 8454 final of the European Commission of 7 December 2016;

(3) Order the European Commission to pay the costs incurred by ClientEarth and to bear its own costs. The European Chemicals Agency must bear its own costs.

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1 Original language: German.

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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 (OJ 2006 L 396, p. 1); the relevant version is as amended by Commission Regulation (EU) 2016/217 of 16 February 2016 (OJ 2016 L 40, p. 1).

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3 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).

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4 Convention on access to information, public participation in decision-making and access to justice in environmental matters of 1998 (OJ 2005 L 124, p. 4), approved by Council Decision 2005/370/EC of 17 February 2005 (OJ 2005 L 124, p. 1).

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5 Commission Regulation of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') (OJ 2011 L 44, p. 2).

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6 Also known as endocrine disruptors. Such substances influence hormone balance.

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7 The challenge to that decision was rejected by the judgments of the General Court of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329), and of the Court of Justice of 23 January 2019, *Deza* v *ECHA* (C-419/17 P, EU:C:2019:52).

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8 Implementing decision C(2017) 4462 final (https://echa.europa.eu/documents/10162/88c20879-606b-03a6-11e4-9edb90e7e615).

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9 That document, which bears the reference 'ECHA/RAC/SEAC Opinion No AFA-O-0000004151-87-17/D', is entitled 'Opinion on an Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP) use: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends'.

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10 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2008 L 312, p. 3).

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11 Judgment of 12 September 2019, *TestBioTech and Others* v *Commission* (C-82/17 P, EU:C:2019:719). On the other hand, the judgments of 13 January 2015, *Council and Others* v *Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht* (C-401/12 P to C-403/12 P, EU:C:2015:4) and *Council and Commission* v *Stichting Natuur en Milieu and Pesticide Action Network Europe* (C-404/12 P and C-405/12 P, EU:C:2015:5), and of 3 September 2020, *Mellifera* v *Commission* (C-784/18 P, not published, EU:C:2020:630), concerned the applicability of that procedure.

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12 See my Opinion in *Bayer CropScience and Bayer* v *Commission* (C-499/18 P, EU:C:2020:735, point 57 et seq. and the case-law cited).

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13 See above, point 19.

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14 Opinion of 22 October 2014 (cited in footnote 9), section 10, p. 17.

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15 Fourth paragraph of the notes on Article 57 of the 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} {SEC(2003) 1171} /* COM(2003) 644 final – COD 2003/0256 */.

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16 Judgments of 29 October 1980, *Roquette Frères* v *Council* (138/79, EU:C:1980:249, paragraph 25); of 25 June 1997, *Italy* v *Commission* (C-285/94, EU:C:1997:313, paragraphs 22 and 23); and of 9 November 2006, *Agraz and Others* v *Commission* (C-243/05 P, EU:C:2006:708, paragraph 73).

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17 Judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443, paragraph 77); of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 57); and of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882, paragraph 35).

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18 Judgments of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraph 51); of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 75); and of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraph 46 and the case-law cited and paragraph 94).

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19 Judgment of 28 March 2019, *Verlezza and Others* (C-487/17 to C-489/17, EU:C:2019:270, paragraph 57). See also judgments of 29 July 2019, *Inter-Environnement Wallonie and Bond Beter Leefmilieu Vlaanderen* (C-411/17, EU:C:2019:622, paragraph 134); of 10 October 2019, *Luonnonsuojeluyhdistys Tapiola* (C-674/17, EU:C:2019:851, paragraph 66); and of 24 October 2019, *Prato Nevoso Termo Energy* (C-212/18, EU:C:2019:898, paragraph 58).

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20 See Articles 1(1) and recitals 1, 3 and 7 of the REACH Regulation and its legal basis, Article 95(3) EC (now Article 114(3) TFEU), Article 3(3) TEU and Articles 35 and 37 of the Charter of Fundamental Rights.

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21 Judgment of the General Court of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329, paragraph 145).

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22 Judgment of the Court of Justice of 23 January 2019, *Deza* v *ECHA* (C-419/17 P, EU:C:2019:52).

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23 Section 3.2(i) of the contested review decision.

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24 Judgments of 7 February 1979, *France* v *Commission* (15/76 and 16/76, EU:C:1979:29, paragraph 7); of 10 July 1986, *Belgium* v *Commission* (234/84, EU:C:1986:302, paragraph 16); of 17 May 2001, *IECC* v *Commission* (C-449/98 P, EU:C:2001:275, paragraph 87); of 15 April 2008, *Nuova Agricast* (C-390/06, EU:C:2008:224, paragraph 54 et seq.); and of 10 September 2019, *HTTS* v *Council* (C-123/18 P, EU:C:2019:694, paragraph 37).

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25 See above, point 19.

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26 See above, point 44.

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27 Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), Opinion on a Review Report for: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends (ECHA/RAC/SEAC: AFA-O-0000006672-71-01/D) of 30 November 2018.

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28 Judgments of 12 September 2019, *TestBioTech and Others* v *Commission* (C-82/17 P, EU:C:2019:719, paragraph 37), and of 3 September 2020, *Mellifera* v *Commission* (C-784/18 P, not published, EU:C:2020:630, paragraph 63).

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29 Judgments of 12 September 2019, *TestBioTech and Others* v *Commission* (C-82/17 P, EU:C:2019:719, paragraph 38), and of 3 September 2020, *Mellifera* v *Commission* (C-784/18 P, not published, EU:C:2020:630, paragraph 64).

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30 Judgment of 12 September 2019, *TestBioTech and Others* v *Commission* (C-82/17 P, EU:C:2019:719, paragraph 38).

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31 Judgment of 12 September 2019, *TestBioTech and Others* v *Commission* (C-82/17 P, EU:C:2019:719, paragraph 39).

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32 Judgments of 29 September 1998, *Commission* v *Germany* (C-191/95, EU:C:1998:441, paragraph 55), and of 14 October 2010, *Commission* v *Austria* (C-535/07, EU:C:2010:602, paragraph 41).

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33 Judgment of 13 March 2007, *OHIM* v *Kaul* (C-29/05 P, EU:C:2007:162, in particular paragraphs 53 and 54).

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34 Judgments of 1 June 1994, *Commission* v *Brazzelli Lualdi and Others* (C-136/92 P, EU:C:1994:211, paragraph 59); of 29 September 2011, *Elf Aquitaine* v *Commission* (C-521/09 P, EU:C:2011:620, paragraph 35); and of 17 December 2020, *De Masi and Varoufakis* v *ECB* (C-342/19 P, EU:C:2020:1035, paragraph 34).

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35 See the references in footnote 24.

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36 Judgments of 20 December 2017, *Protect Natur-, Arten- und Landschaftsschutz Umweltorganisation* (C-664/15, EU:C:2017:987, paragraphs 88 and 89), and of 14 January 2021, *Stichting Varkens in Nood* (C-826/18, EU:C:2021:7, paragraph 63).

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37 See judgment of 19 September 2002, *Germany* v *Commission* (C-377/99, EU:C:2002:504, paragraph 68); with regard to appeals, judgments of 24 September 2002, *Falck and Acciaierie di Bolzano* v *Commission* (C-74/00 P and C-75/00 P, EU:C:2002:524, paragraph 178); of 18 January 2007, *PKK and KNK* v *Council* (C-229/05 P, EU:C:2007:32, paragraph 66); of 10 April 2014, *Areva and Others* v *Commission* (C-247/11 P and C-253/11 P, EU:C:2014:257, paragraph 114); and of 28 July 2016, *Tomana and Others* v *Council and Commission* (C-330/15 P, not published, EU:C:2016:601, paragraph 33); and, with regard to treaty infringement proceedings, judgments of 26 April 2005, *Commission* v *Ireland* (C-494/01, EU:C:2005:250, paragraph 38); and of 11 July 2013, *Commission* v *Netherlands* (C-576/10, EU:C:2013:510, paragraphs 31 and 32).

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38 With regard to appeals, judgments of 18 January 2007, *PKK and KNK* v *Council* (C-229/05 P, EU:C:2007:32, paragraph 64); of 10 July 2008, *Bertelsmann and Sony Corporation of America* v *Impala* (C-413/06 P, EU:C:2008:392, paragraph 63); and of 24 September 2009, *Erste Bank der österreichischen Sparkassen* v *Commission* (C-125/07 P, C-133/07 P and C-137/07 P, EU:C:2009:576, paragraph 310).

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39 Judgment of 28 March 2019, *Tallinna Vesi* (C-60/18, EU:C:2019:264, paragraphs 20 and 21).

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40 Judgment of 24 October 2019, *Prato Nevoso Termo Energy* (C-212/18, EU:C:2019:898, paragraph 58).

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41 See above, in particular point 83.

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42 See above, point 85.

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43 Judgment of 12 September 2019, *TestBioTech and Others* v *Commission* (C-82/17 P, EU:C:2019:719, paragraph 69).

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44 Judgments of 21 July 2011, *Nickel Institute* (C-14/10, EU:C:2011:503, paragraph 60) and *Etimine* (C-15/10, EU:C:2011:504, paragraph 60); and orders of 22 May 2014, *Bilbaína de Alquitranes and Others* v *ECHA* (C-287/13 P, not published, EU:C:2014:599, paragraph 19); and of 4 September 2014, *Rütgers Germany and Others* v *ECHA* (C-288/13 P, not published, EU:C:2014:2176, paragraph 25); *Cindu Chemicals and Others* v *ECHA* (C-289/13 P, not published, EU:C:2014:2175, paragraph 25); and *Rütgers Germany and Others* v *ECHA* (C-290/13 P, not published, EU:C:2014:2174, paragraph 25). See also judgments of the General Court of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329, paragraphs 163 and 164), and of the Court of Justice of 23 January 2019, *Deza* v *ECHA* (C-419/17 P, EU:C:2019:52, paragraph 82).

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45 Judgment of 21 May 2015, *Schräder* v *CPVO* (C-546/12 P, EU:C:2015:332).

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46 Judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443, paragraph 76), and of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 56).

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47 Judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443, paragraph 77); of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 57); and of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882, paragraph 35).

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48 Judgments of 29 October 1980, *Roquette Frères* v *Council* (138/79, EU:C:1980:249, paragraph 25); of 25 June 1997, *Italy* v *Commission* (C-285/94, EU:C:1997:313, paragraphs 22 and 23); and of 9 November 2006, *Agraz and Others* v *Commission* (C-243/05 P, EU:C:2006:708, paragraph 73).

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49 At present, aside from the authorisation at issue, there is only one authorisation for the use of DEHP for aero engines, while three broader applications for authorisation have been pending since 2013 (https://echa.europa.eu/applications-for-authorisation-previous-consultations?diss=true&search_criteria_ecnumber= 204-211-0&search_criteria_casnumber= 117-81-

7&search_criteria_name=Bis%282-ethylhexyl%29+phthalate). Those applications allow the manufacturer, pursuant to Article 56(1)(d) of the REACH Regulation, to continue to place DEHP on the market for the uses applied for.

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50 Point 51 of Annex XVII to the REACH Regulation prohibited use for toys and childcare articles until 7 July 2020. Since then, use is generally prohibited, with some exceptions.

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51 Recital 5 of the authorisation decision.