Provisional text

JUDGMENT OF THE COURT (First Chamber)

25 February 2021 (*)

(Appeal – Regulation (EC) No 1907/2006 – Registration, evaluation, authorisation and restriction of chemicals – European Commission decision authorising certain uses of lead sulfochromate yellow and lead chromate molybdate sulfate red, substances listed in Annex XIV of that regulation – Substances of very high concern – Conditions of authorisation – Assessment of the lack of suitable alternatives)

In Case C-389/19 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 20 May 2019,

European Commission, represented initially by R. Lindenthal, K. Mifsud-Bonnici and G. Tolstoy, and subsequently by R. Lindenthal and K. Mifsud-Bonnici, acting as Agents, and K. Nordlander, advokat,

applicant,

the other parties to the proceedings being:

Kingdom of Sweden, represented initially by C. Meyer-Seitz, H. Shev, J. Lundberg, H. Eklinder and A. Falk, and subsequently by O. Simonsson, C. Meyer-Seitz, M. Salborn Hodgson, R. Shahsavan Eriksson, H. Shev and H. Eklinder, acting as Agents,

applicant at first instance,

Kingdom of Denmark, represented initially by J. Nymann-Lindegren, M.S. Wolff and P.Z.L. Ngo, and subsequently by J. Nymann-Lindegren and M.S. Wolff, acting as Agents,

Republic of Finland, represented by S. Hartikainen, acting as Agent,

European Parliament, represented by A. Neergaard, A. Tamás and C. Biz, acting as Agents,

European Chemicals Agency (ECHA), represented initially by M. Heikkilä, W. Broere and C. Schultheiss, and subsequently by M. Heikkilä, W. Broere and J. Löfgren, acting as Agents,

interveners at first instance,

THE COURT (First Chamber),

composed of J.-C. Bonichot (Rapporteur), President of the Chamber, L. Bay Larsen, C. Toader, M. Safjan and N. Jääskinen, Judges,

Advocate General: E. Tanchev,

Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing of 7 July 2020,

after hearing the Opinion of the Advocate General at the sitting on 29 October 2020,

gives the following

Judgment

1 By its appeal, the European Commission seeks to have set aside the judgment of the General Court of the European Union of 7 March 2019, *Sweden* v *Commission* (T-837/16, 'the judgment under appeal', EU:C:2019:144), by which that Court annulled Commission Implementing Decision C(2016) 5644 final of 7 September 2016 authorising certain uses of lead sulfochromate yellow and lead chromate molybdate sulfate red in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('the decision at issue').

Legal context

2 Under recitals 4, 12, 69, 70, 72 and 73 of 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, and corrigendum OJ 2007 L 136, p. 3; 'the REACH Regulation'):

'(4) Pursuant to the implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development, the European Union is aiming to achieve that, by 2020, chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment.

…

(12) An important objective of the new system to be established by this Regulation is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. …

…

(69) 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. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.

(70) Adverse effects on human health and the environment from substances of very high concern should be prevented through the application of appropriate risk management measures to ensure that any risks from the uses of a substance are adequately controlled, and with a view to progressively substituting these substances with a suitable safer substance. Risk management measures should be applied to ensure, when substances are manufactured, placed on the market and used, that exposure

to these substances including discharges, emissions and losses, throughout the whole life-cycle is below the threshold level beyond which adverse effects may occur. For any substance for which authorisation has been granted, and for any other substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects. Measures to ensure adequate control should be identified in any Chemical Safety Report. These measures should be applied and, where appropriate, recommended to other actors down the supply chain.

…

(72) To support the aim of eventual replacement of substances of very high concern by suitable alternative substances or technologies, all applicants for authorisation should provide an analysis of alternatives considering their risks and the technical and economic feasibility of substitution, including information on any research and development the applicant is undertaking or intends to undertake. Furthermore, authorisations should be subject to time limited review whose periods would be determined on a case-by-case basis and normally be subject to conditions, including monitoring.

(73) Substitution of a substance on its own, in a preparation or in an article should be required when manufacture, use or placing on the market of that substance causes an unacceptable risk to human health or to the environment, taking into account the availability of suitable safer alternative substances and technologies, and the socio-economic benefits from the uses of the substance posing an unacceptable risk.'

3 Article 55 of the REACH Regulation, entitled 'Aim of authorisation and considerations for substitution', provides as follows:

'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.'

4 Article 56(1) of that regulation, in the version applicable to the facts of the dispute, provides:

'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

(b) 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 exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or

(c) the date referred to in Article 58(1)(c)(i) has not been reached; 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;

(e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.'

5 Article 58(1) of that regulation states as follows:

'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 ('the sunset date') which should take into account, where appropriate, the production cycle specified for that use;

(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;

…'

6 Under Article 60 of that 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.

…

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. 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 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.

…’

7 Article 64 of the REACH Regulation provides that the European Chemicals Agency (ECHA) is to consult the public and its Committees for Risk Assessment and for Socio-economic Analysis.

8 Pursuant to Article 133 of that Regulation, the Commission is to be assisted by a committee (‘the REACH Committee’).

Background to the dispute

9 The background to the dispute is set out in paragraphs 1 to 30 of the judgment under appeal and may, for the purposes of the present proceedings, be summarised as follows.

10 Lead sulfochromate yellow and lead chromate molybdate sulfate red are pigments widely used, due to their durability, light colour and brilliance, in varnishes and paints, in particular for bridges or iron constructions, to fulfil a signalling function or for yellow road markings.

11 Those pigments have been included by Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV of Regulation 1907/2006 (OJ 2012 L 41, p. 1) in the list of substances of very high concern in that annex, due to their carcinogenic and toxic properties for human reproduction. Consequently, their placing on the market and use have been subject to authorisation since 21 May 2015.

12 On 19 November 2013, DCC Maastricht BV submitted an application for authorisation to place the two pigments in question on the market for six uses, which are identical for both substances. That application contains the following non-exhaustive examples of products covered by the uses covered thereby and which, according to the applicant, require the technological performance provided by the pigments: boot covers for cars, warning signs, containers for pharmaceutical waste, tubing for the petrochemical industry, cranes, agricultural machinery, road equipment, steel bridges, steel vaults and steel containers.

13 In accordance with Article 64(2) of the REACH Regulation, ECHA carried out a public consultation in order to give interested third parties the opportunity of submitting information on alternative substances or techniques. In the context of that consultation, opinions were submitted by EU manufacturers, downstream users of the pigments at issue, sector organisations, Member States and some non-governmental organisations. Subsequently, pursuant to Article 64(3) et seq. of that regulation, the Committee for Risk Assessment and the Committee for Socio-economic Analysis delivered opinions on each of the uses concerned.

14 Lastly, the application for authorisation was examined by the REACH Committee. During the discussions in that committee, two Member States and the Kingdom of Norway stated that those lead chromates were not used as pigments in paint intended for yellow road marking on their national territory. In one of those Member States, the use of lead chromates for road markings was prohibited 20 years ago. The Commission submitted its draft decision to the vote of the members of the REACH Committee. Twenty-

three Member States voted in favour of the draft, while three Member States, including the Kingdom of Sweden, voted against it. Two Member States abstained.

15 On 7 September 2016, the Commission adopted the decision at issue.

16 The requested authorisation was not granted on the basis of Article 60(2) of the REACH Regulation, since the Commission was of the view that the risk was not adequately controlled. By the decision at issue, however, it authorised the uses covered by the application on the basis of Article 60(4) of that regulation, subjecting that authorisation to restrictions and requirements.

17 In Article 1(1) and (2) of the decision at issue, the Commission authorised the uses of the lead chromates in question, as set out in the application for authorisation, under the condition that the performance of the pigment premixes, paints and pre-compounds containing the substances concerned, or of finished articles containing them, in terms of shade functionality and chroma, opacity (hiding power), dispersibility, 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.

18 Article 1(3)(c) of the decision limits the amount of lead sulfochromate yellow and the amount of lead chromate molybdate sulfate red that may be placed on the market by the authorisation holder for the authorised uses to 2 100 tonnes per year and 900 tonnes per year respectively.

19 Under Article 1(3)(d) of the decision at issue, authorisation for all uses is subject to the condition that users downstream of the authorisation holder must provide ECHA, by 30 June 2017 at the latest, with information on the suitability and availability of alternatives for the uses concerned, giving detailed proof of the need to use the substances in question.

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

21 Article 1(4) of the decision at issue provides, in essence, as regards uses for road marking, that the authorisation is not to apply in Member States where national legislation prohibits the use of lead chromates in such marking.

22 Finally, under Article 2(2) of that decision, the review period referred to in Article 60(9)(e) of the REACH Regulation expires on 21 May 2019 for two uses of the substances at issue, namely the professional use of paints on metal surfaces and the professional use of premixes and solid or liquid coloured pre-compounds containing pigments for the application of thermoplastic road marking, and on 21 May 2022 for the other four uses authorised by that decision.

The procedure before the General Court and the judgment under appeal

23 By application lodged at the Registry of the General Court on 28 November 2016, the Kingdom of Sweden brought an action seeking annulment of the decision at issue.

24 By the judgment under appeal, the General Court annulled that decision, on the ground that the Commission had erred in law in its examination of the lack of availability of alternative substances.

Forms of order sought by the parties before the Court of Justice

25 The Commission requests the Court of Justice, principally, to set aside the judgment under appeal and remit the case to the General Court and, in the alternative, if the appeal is dismissed, to order that the

effects of the annulled decision be maintained. ECHA has intervened in support of the Commission.

26 The Kingdom of Sweden requests the Court to dismiss the appeal in its entirety, together with the application to maintain the effects of the annulled decision. The Kingdom of Denmark, the Republic of Finland and the European Parliament have intervened in support of the Kingdom of Sweden.

The appeal

The principal form of order sought, that the judgment under appeal be set aside

27 In support of that form of order sought, the Commission puts forward three grounds of appeal.

The first ground of appeal

– *Arguments of the parties*

28 While the Commission does not dispute the position adopted by the General Court in the judgment under appeal, namely that it is for the applicant to establish the absence of a technically and economically viable solution for the uses in question, it does, however, criticise the level of proof required by that court. The General Court set a level of proof impossible to satisfy, in that it held, in paragraph 79 of the judgment under appeal, that where 'there remain uncertainties as regards the condition relating to the lack of availability of alternatives, it must be concluded that the applicant for authorisation has not discharged the burden of proof'. Indeed, any technical and scientific assessment is by its very nature vitiated by uncertainty, simply because it may be invalidated by information that was not available when it was made. The same error of law was, in the Commission's submission, repeated in paragraphs 81, 85, 86, 90 and 101 of the judgment under appeal.

29 The Commission recognises that alternatives are available on the market for the intended uses, but notes that they do not have the same level of performance as the substance at issue. However, since the Commission applied a threshold of zero for the loss of performance of the alternatives and regards the alternatives as not achieving the desired level of technical performance, it is of the view that it was correct to assume that there was no technically viable alternative.

30 The Kingdom of Sweden, the Kingdom of Denmark and the Parliament contend that that ground of appeal should be dismissed as inadmissible. In addition, they regard it, as does the Republic of Finland, as unfounded.

– *Findings of the Court*

31 By its first ground of appeal, the Commission submits that the General Court required the applicant to demonstrate, in a manner that leaves no uncertainty, the lack of availability of technically and economically viable alternatives for the uses in question. Such a requirement, repeated in paragraphs 79, 81, 85, 86, 90 and 101 of the judgment under appeal, is vitiated by an error of law.

32 However, taken in context, those paragraphs of the judgment under appeal cannot be read as requiring the applicant for authorisation or the Commission to establish with absolute certainty that technically and economically viable alternatives to a particular substance are not available for a given use.

33 It should be noted, indeed, that paragraph 79 of the judgment under appeal follows from the uncontested findings of the General Court in the two preceding paragraphs of that judgment. In paragraph 77 of the judgment, the General Court rightly inferred from the approximation of Article 60(4) and recital 69 of the REACH Regulation that it is for the applicant for authorisation to show that no suitable alternative is available. In the subsequent paragraph of that judgment, it was correct to hold that Article 60(4) and (5) of the REACH Regulation requires the Commission to verify that the conditions laid down in Article 60(4) are in fact satisfied. In paragraph 79 of the judgment under appeal, the General Court concluded, in

essence, from the preceding two paragraphs of that judgment that if, after its examination and in the light of all the evidence provided by the applicant and by other persons or gathered by itself, the Commission is of the view that the applicant fails to adduce the evidence which the burden of proof on the applicant requires, that institution must refuse the authorisation requested. Thus, contrary to the appellant's submissions, paragraph 79 of that judgment does not contain any assessment of the 'level of proof' required of the applicant or admissible by the Commission.

34 Moreover, the General Court noted, in paragraphs 81 and 85 of the judgment under appeal, which it is appropriate to read together, that the Commission's authorisation decision must not be based solely on assumptions that have not been confirmed or have been overturned by the information available to the Commission, in accordance with the case-law of the Court of Justice (see, by analogy, judgment of 17 September 2009, *Commission* v *MTU Friedrichshafen*, C-520/07 P, EU:C:2009:557, paragraphs 52 and 53). Those two paragraphs of the judgment under appeal thus cannot be read as obliging the Commission to require an unreasonable level of proof from the applicant for authorisation.

35 Furthermore, the General Court accepted, in paragraph 86 of the judgment under appeal, that the Commission may grant the requested authorisation where the remaining uncertainties are negligible, provided that the institution makes its decision after having carried out a detailed examination and verified a sufficient amount of material and reliable information, which the General Court considered not to have been the case here. Thus, it did not hold that the Commission was not permitted to leave any uncertainty as to the lack of availability of alternatives.

36 Lastly, paragraph 90 of the judgment under appeal, in which certain items of evidence submitted to the Commission during the public consultation procedure are reported, and paragraph 101 of that judgment, in which the General Court noted that the Commission had not explained why the alternatives referred to by the Kingdom of Sweden could not be used, do not concern the standard of proof that the Commission should require. Paragraph 101, in particular, expresses rather the failure to state reasons in the decision at issue as regards the lack of availability of alternatives with which to replace lead chromates.

37 It follows from the foregoing that, without it being necessary to examine the admissibility of the first ground of appeal, it must be rejected as unfounded.

The third ground of appeal

– *Arguments of the parties*

38 By its third ground of appeal, which it is appropriate to examine before the second, the Commission submits, by the first part of that ground of appeal, that the General Court failed to have regard, throughout its reasoning and, in particular, in paragraphs 86, 97 and 98 of the judgment under appeal, to the fact that the decision at issue constituted a partial authorisation for certain uses of lead chromates for which it had been found that viable alternatives were not available and not an authorisation for all the uses covered by in the application. The contested decision grants an authorisation only in respect of uses for which no alternatives were available.

39 By the second part of the third ground of appeal, the Commission submits that the General Court erred in law in finding that the conditions set out in the decision at issue showed that the lack of availability of alternatives had not been duly established. The Commission is of the view that it should be possible to delimit the scope of the authorisation by means of objective criteria and to define the authorised uses by reference to the functionalities sought, as was done in Article 1(3)(d) and (e) of the decision at issue. It submits that it did not delegate to the competent authorities the discretionary task of assessing the alternatives and that no passage of that decision can be understood in that sense. To confuse the limitation of the scope of an authorisation with the failure to carry out the assessment of alternatives, or not to allow Member States to carry out tasks to monitor compliance and verification in the context of an authorisation system for a given substance, would amount to disregarding the allocation of competences provided for in the REACH Regulation and could have adverse consequences for human health and the environment.

40 The Kingdom of Sweden, the Kingdom of Denmark, the Republic of Finland and the Parliament contend that the third ground of appeal should be rejected on the merits and the Kingdom of Denmark contends in addition that it is inadmissible.

– *Findings of the Court*

41 By its third ground of appeal, the Commission complains that the General Court misinterpreted the decision at issue by holding, in paragraphs 86, 97 and 98 of the judgment under appeal, first, that it authorised all the uses covered by the application, whereas it granted only partial authorisation, and, second, that the Commission had not completed its assessment of the lack of availability of alternatives in accordance with Article 60(4) of the REACH Regulation.

42 In the first place, it must be noted that in none of the paragraphs cited, contrary to the Commission's submissions, did the General Court hold that the contested decision authorised all the uses covered by the application. When interpreting Article 1(1) and (2) of that decision in paragraph 97 of the judgment under appeal, the General Court found, on the contrary, that 'the statement that use of the lead chromates at issue in the present case is limited solely to those cases in which the performance of the compositions of substances containing those chromates is really necessary amounts to a declaration that a downstream user, whenever he identifies an alternative, should refrain from using the lead chromates at issue in the present case'. Consequently, the first part raised in support of the third ground of appeal lacks any factual basis.

43 In the second place, it is true that the General Court held that the Commission had not carried out an adequate examination of the alternatives. In reaching that conclusion, the General Court found, in paragraph 81 of the judgment under appeal, that Article 60(4) of the REACH Regulation does not allow the Commission to adopt an authorisation decision on the basis of mere hypotheses, which is not contested by the Commission in the present appeal proceedings. It then set out, in particular in paragraphs 97 and 98, referred to by the Commission, the considerations leading it to conclude that the Commission had not succeeded in extricating itself from the state of uncertainty in which it found itself as regards the availability of alternatives.

44 In that regard, it should be noted, first, that in paragraph 97 of the judgment under appeal, the General Court interpreted to that effect the fact that, in Article 1(1) and (2) of the decision at issue, the Commission had formally limited the authorisation for use of the lead chromates at issue solely to those cases in which that use was necessary. Although the Commission criticises that interpretation and argues that it granted only a limited authorisation for certain uses, it must nevertheless be noted that the restriction in Article 1(1) and (2) of that decision is not a true restriction, since it merely recalls one of the general conditions for authorisation of a substance of very high concern laid down in Article 60(4) of the REACH Regulation and it is therefore not possible to define the scope of that restriction.

45 Second, the General Court held, in paragraph 98 of the judgment under appeal, that Article 1(3)(d) of the decision at issue reflected that uncertainty on the part of the Commission, in that it required the downstream users of the authorisation holder to provide ECHA, by 30 June 2017 at the latest, with information on the suitability and availability of alternatives, giving detailed proof of the need to use the substances in question. That provision effectively requires downstream users to provide additional information for assessment of the condition of the lack of availability of alternatives for the uses concerned, after those uses have been authorised by the Commission. Article 60(4) of the REACH Regulation does not allow the Commission to authorise the use of a substance of very high concern if another suitable substance can be substituted for it. Consequently, the Commission cannot grant such authorisation before having duly ascertained that there is no available alternative.

46 It follows from the foregoing that the General Court was entitled to hold that the Commission had failed to fulfil its obligation to verify the lack of availability of alternatives for the various uses of lead chromates considered. The second part raised in support of the third ground of appeal must therefore be rejected.

47 It follows that, without it being necessary to examine its admissibility, the third ground of appeal must be rejected as unfounded.

The second ground of appeal

– *Arguments of the parties*

48 The Commission submits that the General Court was in error, in particular in paragraphs 86, 90 and 96 of the judgment under appeal, as to the scope of its review of the evaluation of the technical and economic feasibility of alternatives. It argues that the General Court took the place of the Commission as regards the weighing up of social, economic and technical considerations, disregarding the discretion possessed by the Commission.

49 The General Court considered, in paragraphs 86 and 90, that the Commission remained uncertain as to the lack of alternatives and that, consequently, it failed to have regard to its duty of diligence. However, such uncertainty is not apparent from the decision at issue, which, on the contrary, clearly states that the Commission had chosen, at its discretion, to apply a threshold which presupposed that alternative substances did not have a lower technical performance, then considered that no alternative reached that threshold. The General Court believed it possible to detect uncertainty and, consequently, attributed a lack of diligence to the Commission since it had failed to distinguish those two stages. It is impossible to evaluate the technical feasibility of an alternative without first deciding, on a discretionary basis, the level of loss of performance which can be regarded as acceptable.

50 That is why the assessment of alternatives falls within a review of manifest error, as the General Court, moreover, correctly held in paragraphs 246 and 248 of its judgment of 4 April 2019, *ClientEarth* (T-108/17, EU:T:2019:215). However, in the judgment under appeal, the General Court did not in any way find that the Commission had committed such a manifest error in setting the acceptable level of loss of technical performance or in the assessment, in the light of that threshold, of the available alternatives.

51 The Kingdom of Sweden, the Kingdom of Denmark and the Parliament contend that the second ground of appeal should be rejected as inadmissible. In any event, they are of the view, as is the Republic of Finland, that that ground of appeal is unfounded.

– *Findings of the Court*

52 By its second ground of appeal, the Commission submits that the General Court erred, in particular in paragraphs 86, 90 and 96, as to the Commission's discretion under Article 60(4) of the REACH Regulation as regards setting the threshold for the loss of technical performance and, accordingly, as regards the intensity of the judicial review which it is for that Court to exercise over the Commission's decisions taken under that provision.

53 In the first place, it must be noted that paragraph 86 of the judgment under appeal contains no general assertion concerning the Commission's discretion to set the threshold for loss of technical performance. However, the General Court criticised the Commission's assessment of the condition relating to the lack of availability of alternatives. In its view, the Commission granted the authorisation prematurely, before having duly completed its examination of that condition. Paragraph 86 thus contains only an assessment of the facts which it is not, in principle, for the Court of Justice to review in the context of an appeal.

54 Nor is such an assertion apparent from paragraphs 90 and 96 of the judgment under appeal. In paragraph 90 of the judgment under appeal, the General Court merely referred to the fact that, according to one of the stakeholders in the public consultation procedure, it could be concluded that, under certain conditions, alternatives were available on the EU market for all the uses covered by the application for authorisation. Similarly, in paragraph 96 of that judgment, the General Court merely held that it was apparent from recitals 8, 9 and 12 of the decision at issue that, at the date of that decision, the Commission continued to have doubts as to the lack of availability of technically feasible alternatives for all the uses

covered by the application. Consequently, neither of those two paragraphs of the judgment under appeal is vitiated by the error of law alleged.

55 Even were the Commission to have intended to rely on a distortion of the facts by the General Court, it is clear from the case file before the Court of Justice that such a complaint is unfounded. That complaint is contradicted by the documents in the file and, in particular, by the decision at issue itself. In that regard, as has been noted in paragraphs 44 and 45 of the present judgment, it is clear that that decision reveals the state of persistent uncertainty in which the Commission found itself as regards the lack of availability of alternatives.

56 Finally, if it were accepted that the decision at issue could be regarded as being based on the Commission's application of a threshold of zero for the loss of technical performance, that would render that decision unlawful, since it is based on an interpretation of Article 60 of the REACH Regulation which is entirely contrary to the very purpose of that regulation. As is apparent in particular from recitals 4, 12, 70 and 73 and Article 55 of that regulation, it seeks to promote the replacement of substances of very high concern by suitable alternative substances. However, to decide, as a matter of principle, that replacement must not entail any reduction in performance not only amounts to adding a condition not provided for in that regulation, but is likely to prevent that replacement and, consequently, to deprive that regulation of much of its effectiveness.

57 In the second place, it is appropriate to recall that the General Court held that the Commission had not carried out a proper examination of the lack of availability of alternatives and that, accordingly, the authorisation could not have been validly granted. However, the General Court cannot be criticised for having substituted itself for the Commission in assessing the alternatives, since, on the contrary, it relied on the Commission's assessment of those alternatives, as set out in the decision at issue, and on the persistent uncertainties as to the lack of availability of alternatives which are apparent from that decision.

58 Accordingly, without there being any need to examine its admissibility, the second ground of appeal must be rejected.

59 It follows from the foregoing that the form of order sought in the appeal seeking to have the judgment under appeal set aside must be rejected.

The form of order sought in the alternative, seeking the provisional maintenance of the effects of the decision at issue

Arguments of the parties

60 The Commission accepts that it took an erroneous position before the General Court regarding the legal effects of the annulment of the decision at issue, arguing that the annulment of that decision would have the effect of prohibiting the placing on the market of the substances in question. That reasoning was taken up by the General Court and by the other parties to the proceedings.

61 Article 56(1) of the REACH Regulation provides for a transitional scheme, under which an applicant may place the substance for which he has applied for authorisation on the market until the Commission adopts a decision on his application for authorisation. In so doing, the annulment of that decision would have the consequence of re-establishing the legal situation existing before its adoption, that is to say, the transitional scheme under which the placing on the market of the substance is authorised. The annulment with immediate effect of that decision would therefore have effects contrary to the purpose with a view to which the General Court refused provisionally to maintain the effects of the annulled decision, namely the protection of human health.

62 Thus, the Commission requests the Court to repeal point 2 of the operative part of the judgment under appeal and to order that the effects of the decision at issue be maintained, in the interests of legal certainty and the protection of human health.

63 ECHA supports that form of order sought by the Commission.

64 The Kingdom of Sweden, the Kingdom of Denmark and the Republic of Finland request the Court to reject that claim.

– *Findings of the Court*

65 The sole ground of appeal put forward in support of the form of order sought in the alternative alleges that the General Court erred in law in paragraph 112 of the judgment under appeal as regards the effects of the annulment which it ordered.

66 The General Court held, in that paragraph, that the annulment with immediate effect of the authorisation decision would prevent the applicant, DCC Maastricht, from continuing to market the pigments in question and that, although that annulment was likely to entail serious adverse consequences for that company, it was justified by the concern to protect human health from the effects of those dangerous substances.

67 However, in the circumstances of the present case, the outright annulment of the decision at issue has had the effect, quite to the contrary, of authorising DCC Maastricht to continue marketing the pigments at issue until the Commission has adopted a new decision, as envisaged by the Vice-President of the Court in her order for interim measures of 21 November 2019, *Commission* v *Sweden* (C-389/19 P-R, not published, EU:C:2019:1007, paragraph 60). The authorisations in question had been granted in a previous regulation, namely Regulation No 125/2012, until 21 May 2015.

68 Under the combined provisions of Article 56(1)(d) and Article 58(1)(c) of the REACH Regulation, the continuation of uses already authorised is permitted after the expiry date of their authorisation until a decision has been taken on the new application for authorisation, provided that the new application for authorisation has been submitted at least 18 months before the expiry date of the authorisation. DCC Maastricht, having applied for a new authorisation within the prescribed period, benefited from that transitional scheme until the adoption of the decision at issue and thus regained the benefit of it following the annulment with immediate effect of that decision.

69 It follows 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) of the REACH Regulation. Since the form of order sought in the alternative by the Commission is well founded, point 2 of the operative part of the judgment under appeal must be set aside.

The dispute

70 In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, if the Court quashes the decision of the General Court, it may itself give final judgment in the matter, where the state of the proceedings so permits.

71 That is the case with the present proceedings. It is therefore necessary to examine the application for the maintenance of the effects of the annulled decision, brought by the Commission before the General Court and renewed before the Court of Justice.

72 Under the second paragraph of Article 264 TFEU, the Court may, if it considers it necessary to do so, state which of the effects of an act which it has declared void are to be considered definitive. In exercising the power conferred on it by that article, the Court is to have regard to respect for the principle of legal certainty and other public or private interests (see, to that effect, judgments of 6 September 2012, *Parliament* v *Council*, C-490/10, EU:C:2012:525, paragraph 91; of 22 October 2013, *Commission* v *Council*, C-137/12, EU:C:2013:675, paragraph 81; of 24 June 2014, *Parliament* v *Council*, C-658/11, EU:C:2014:2025, paragraphs 90 and 91, and of 7 September 2016, *Germany* v *Parliament and Council*, C-113/14, EU:C:2016:635, paragraph 83).

73 As stated in paragraph 67 of the present judgment, the annulment of the decision at issue has the effect of extending the duration of the authorisation of the pigments in question beyond 21 May 2015. However, the decision at issue restricted, in certain respects, the use of those substances of very high concern. Article 1(3)(c) of the decision, for example, limited the amount of lead sulfochromate yellow and the amount of lead chromate molybdate sulfate red which could be placed on the market by the holder of the authorisation for the authorised uses to 2 100 tonnes per year and 900 tonnes per year respectively. Similarly, under Article 2(2) of that decision, the review period referred to in Article 60(9)(e) of the REACH Regulation in respect of two specific uses of two lead chromate pigments, namely the professional use of paints on metal surfaces or the professional use of premixes and solid or liquid colour pre-compounds containing pigments for the application of thermoplastic road markings, would have expired on 21 May 2019 if the decision at issue had not been annulled or if its effects had been maintained. The authorisation holder had not submitted requests for review for those specific uses within the prescribed period.

74 It follows from the foregoing that rejection of the application to maintain the effects of the decision at issue would increase the risk of serious and irreparable damage to human health and the environment. Consequently, it is necessary to order that the effects of that decision be maintained until the Commission has adopted a fresh decision on the application for authorisation submitted by DCC Maastricht.

Costs

75 Under Article 138(1) of the Rules of Procedure of the Court of Justice, applicable to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Although the Commission is, for the most part, the losing party in the present proceedings, neither the Kingdom of Sweden nor any of the interveners in support of it have applied for the Commission or ECHA, which intervened in support of the Commission, to be ordered to pay the costs. Consequently, each party and intervener must be ordered to bear its own costs relating to the appeal proceedings.

On those grounds, the Court (First Chamber) hereby:

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

2. **Dismisses the appeal as to the remainder;**

3. **Orders the effects of Commission Implementing Decision C(2016) 5644 final of 7 September 2016 authorising certain uses of lead sulfochromate yellow and lead chromate molybdate sulfate red in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council to be maintained until the European Commission has adopted a fresh decision on the application for authorisation submitted by DCC Maastricht BV;**

4. **Orders the European Commission, the Kingdom of Sweden, the Kingdom of Denmark, the Republic of Finland, the European Parliament and the European Chemicals Agency (ECHA) each to bear their own costs relating to the appeal proceedings.**

[Signatures]

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* Language of the case: Swedish.