Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

20 April 2023*

(Action for annulment – Implementing Decision C(2020) 8797 – Authorisation of certain uses of chromium trioxide – Regulation (EC) No 1907/2006 – Registration, evaluation, authorisation and restriction of chemicals – Article 60 – Granting of authorisations – Obligation to demonstrate that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies – Article 62 – Applications for authorisation – Article 64 – Procedure for authorisation decisions)

In Case C-144/21,

ACTION for annulment under Article 263 TFEU, brought on 5 March 2021,

European Parliament, represented by C. Ionescu Dima, M. Menegatti and L. Visaggio, acting as Agents,

applicant,

v

European Commission, represented by R. Lindenthal and K. Mifsud-Bonnici, acting as Agents,

defendant,

supported by:

European Chemicals Agency (ECHA), represented by W. Broere, M. Heikkilä and T. Zbihlej, acting as Agents,

intervener,

THE COURT (Fourth Chamber),

composed of C. Lycourgos, President of the Chamber, L.S. Rossi, J.-C. Bonichot (Rapporteur), S. Rodin and O. Spineanu-Matei, Judges,

Advocate General: G. Pitruzzella,

Registrar: A. Calot Escobar,

* Language of the case: English.

having regard to the written procedure,

after hearing the Opinion of the Advocate General at the sitting on 27 October 2022,

gives the following

Judgment

1 By its application, the European Parliament asks the Court to annul Article 1(1) and (5) and Articles 2 to 5, 7, 9 and 10 of Commission Implementing Decision C(2020) 8797 of 18 December 2020 partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Chemservice GmbH and others) ('the contested decision'), inasmuch as those articles concern the authorisation for uses 2, 4 and 5, as well as use 1 in relation to the formulation of mixtures for uses 2, 4 and 5.

Legal context

2 According to recitals 1, 8, 12, 22, 69, 70, 72, 73, 77, 82 and 119 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), as amended by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 (OJ 2008 L 353, p. 1) ('the REACH Regulation'):

'(1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in mixtures and in articles, while enhancing competitiveness and innovation. This Regulation should also promote the development of alternative methods for the assessment of hazards of substances.

…

(8) Special account should be taken of the potential impact of this Regulation on small- and medium-sized enterprises (SMEs) and the need to avoid any discrimination against them.

…

(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. …

(22) The authorisation provisions should ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. Authorisations for the placing on the market and use should be granted by the [European] Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.

…

(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 mixture 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.

…

(77) In view of workability and practicality considerations, both as regards natural or legal persons, who have to prepare application files and take appropriate risk management measures, and as regards the authorities, who have to process authorisation applications, only a limited number of substances should be subjected to the authorisation procedure at the same time and realistic deadlines should be set for applications, while allowing certain uses to be exempted. Substances identified as meeting the criteria for authorisation should be included in a candidate list for eventual inclusion in the authorisation procedure. Within this list, substances on the Agency's work programme should be clearly identified.

…

(82) To allow effective monitoring and enforcement of the authorisation requirement, downstream users benefiting from an authorisation granted to their supplier should inform the Agency of their use of the substance.

…

(119) Apart from their participation in the implementation of Community legislation, Member State competent authorities should, because of their closeness to stakeholders in the Member States, play a role in the exchange of information on risks of substances and on the obligations of natural or legal persons under chemicals legislation. At the same time, close cooperation between the Agency, the Commission and the competent authorities of the Member States is necessary to ensure the coherence and efficiency of the global communication process.'

3 Article 1 of the REACH Regulation, entitled 'Aim and scope', provides, in paragraphs 1 to 3, as follows:

'1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

2. This Regulation lays down provisions on substances and mixtures within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures.

3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.'

4 According to Article 3 of that regulation, entitled 'Definitions':

'For the purposes of this Regulation:

1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

2. mixture: means a mixture or solution composed of two or more substances;

3. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

…

13. downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;

…

18. Agency: means the European Chemicals Agency as established by this Regulation;

…

24. use: means 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;

…

37. exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

38. use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

…'

5 Title VII of the REACH Regulation, which comprises Articles 55 to 66 thereof, concerns the authorisation of 'substances of very high concern', referred to as such on account of their serious and often irreversible effects on human health and the environment.

6 Article 55 of that 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.'

7 Article 56 of that regulation, entitled 'General provisions', provides, in paragraph 1:

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

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

…

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

…'

8 According to Article 57 of the REACH Regulation, entitled 'Substances to be included in Annex XIV':

'The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008 [of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1)];

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;

…'

9 Article 58 of that regulation, entitled 'Inclusion of substances in Annex XIV', states:

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

(a) the identity of the substance as specified in Section 2 of Annex VI;

(b) the intrinsic property (properties) of the substance referred to in Article 57;

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

…

3. …

The number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for. The Agency shall make its first recommendation of priority substances to be included in Annex XIV by 1 June 2009. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV.

…'

10 Pursuant to Commission Regulation (EU) No 348/2013 of 17 April 2013 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 2013 L 108, p. 1), chromium trioxide was included in that annex as a carcinogenic category 1A and mutagenic category 1B substance on the basis of its intrinsic properties.

11 Under Article 60 of the REACH Regulation, entitled 'Granting of authorisations':

'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 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.

…

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

…’

12 Article 62 of that regulation, entitled ‘Applications for authorisations’, provides in paragraph 4:

‘An application for authorisation shall include the following information:

(a) the identity of the substance(s), as referred to in Section 2 of Annex VI;

(b) the name and contact details of the person or persons making the application;

(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) where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.'

13 Article 64 of that regulation, entitled 'Procedure for authorisation decisions', provides:

'1. The Agency shall acknowledge the date of receipt of the application. The Agency's Committees for Risk Assessment and Socio-economic Analysis shall give their draft opinions within ten months of the date of receipt of the application.

2. The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, 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.

…

8. The Commission shall prepare a draft authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article 133(3).

…'

14 Annex I to the REACH Regulation, entitled 'General provisions for assessing substances and preparing chemical safety reports', includes a Section 5, entitled 'Exposure assessment', which states that that assessment is divided into two steps. As regards the second step, relating to 'exposure estimation', point 5.2.4 contains the following text:

'An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) … In particular, the exposure estimation shall take account of:

– adequately measured, representative exposure data,

…'

Background to the dispute

15 Owing to its carcinogenic and toxic properties, chromium trioxide is one of the substances classified as 'of very high concern' listed in Annex XIV to the REACH Regulation. Uses of that substance are subject to the authorisation requirement under Article 56(1)(a) of that regulation.

16 In 2015, Lanxess Deutschland GmbH and other operators ('the applicants for authorisation') submitted an application to obtain authorisation for six categories of uses of chromium trioxide.

17 The six use categories for which authorisation was requested are the following: uses in the formulation of mixtures ('category 1'); uses in functional chrome plating ('category 2'); uses in functional chrome plating with decorative character ('category 3'); uses in surface treatment for applications in the aeronautics and aerospace sectors (unrelated to functional chrome plating with decorative character) ('category 4'); uses in surface treatment (except passivation of tin-plated steel (electrolytic tin plating – ETP)) for applications in various industry sectors, namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to functional chrome plating or functional chrome plating with decorative character) ('category 5'); and uses in passivation of tin-plated steel (ETP) ('category 6').

18 The opinions issued by the Committee for Risk Assessment ('RAC') and the Committee for Socio-economic Analysis ('SEAC'), in accordance with Article 64 of the REACH Regulation, were published in September 2016.

19 On 27 March 2019, the European Parliament adopted a resolution objecting to an earlier draft of the decision. In essence, the Parliament's objection was based on the fact that the information submitted by the applicants for authorisation had serious shortcomings and thus it could not be properly assessed whether the requirements for granting an authorisation, in particular whether safer alternatives were available or not, had been satisfied. In the Parliament's view, that was particularly true since the description of the intended uses of the substance at issue was so generic that it resulted in the authorisation having an extremely broad scope. In that regard, the

Parliament also took the view that the Commission's approach, aimed at remedying the shortcomings in the application by requiring the applicant for authorisation to provide missing data in the review report, was not in line with the judgment of the General Court of 7 March 2019, *Sweden* v *Commission* (T-837/16, EU:T:2019:144).

20 As a result of the Parliament's resolution, the Commission excluded category 3 (uses in functional chrome plating with decorative character) from the scope of its draft decision. For the rest, the Commission maintained its original approach, which was to grant the authorisation subject to certain conditions and restrictions.

21 On 18 December 2020, the Commission adopted the contested decision.

The contested decision

22 In recital 8 of the contested decision, the Commission stated that an authorisation for chromium trioxide could be granted only under Article 60(4) of the REACH Regulation.

23 In recitals 9 to 15, the Commission examined the first of the two conditions laid down in that provision, namely that socio-economic benefits must outweigh the risks to human health or the environment arising from the use of the substance.

24 In particular, recitals 10 to 12 and 15 are worded as follows:

> '(10) Concerning uses 1, 2, 4 and 5, RAC further concluded that there are significant uncertainties regarding worker exposure due to limited availability of measured exposure data. RAC further concluded that a prevalent lack of contextual information has made it difficult to establish a link between the operational conditions and risk management measures described in the application and the claimed exposure levels for specific tasks and sites, thereby preventing RAC from further evaluation. Those uncertainties concern the reliability and representativeness of the exposure data and how it relates to the specific risk management measures in place, particularly for use 4 where, in addition to bath immersion, different activities including spraying, rolling, brushing and machining operations are covered by the application and the applicants [for authorisation] have not been able to fully assess the combined exposure related to all those tasks. Nevertheless the Commission notes that those uncertainties did not prevent SEAC from further analysing the application.
>
> (11) Concerning uses 1, 2, 4 and 5, RAC further concluded that uncertainties also exist in the assessment of exposure of the general population to the substance, via the environment, at the local scale, particularly regarding emission of chromium (VI) via wastewater. This is particularly relevant as regards oral exposure via drinking water. However, RAC considered the provided assessment of risks to the general population via the environment to be sufficient for further analysis by SEAC, noting that the approach by the applicants [for authorisation] is based on assumptions that are likely to overestimate the risks to the general population. Regional exposure, although estimated by the applicants [for authorisation], was not considered relevant by RAC due to transformation of chromium (VI) to non-carcinogenic chromium (III) that occurs rapidly under most environmental conditions.

(12) In its opinions on uses 1, 2, 4 and 5, due to the uncertainties in the assessment of risks to workers and to the general population via the environment, RAC recommended imposing additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with that conclusion.

…

(15) In its opinions as regards uses 1, 2, 4, 5 and 6 of chromium trioxide as described in the application[,] SEAC concluded that the overall socio-economic benefits arising from each of those uses outweigh the risk to human health arising from those uses. … Concerning uses 2, 4, 5 and 6, SEAC noted that the socio-economic benefits arising from the use of the substance, based on the expected profit losses or the social costs due to job losses alone, clearly outweigh the monetised human health impacts, which are calculated on a worst case scenario basis. …'

25 In recitals 16 to 24 of the contested decision, the Commission analysed the second condition laid down in Article 60(4) of the REACH Regulation for granting an authorisation, namely that there must be no suitable alternative substances or technologies.

26 In particular, recitals 18 to 20 and 22 are worded as follows:

'(18) In its opinions on uses 2, 4 and 5, SEAC concluded that there are no suitable alternative substances or technologies. However, due to the very broad scope of the uses applied for, SEAC could not exclude possible uncertainty with regard to the technical feasibility of alternatives for a limited number of specific applications that are covered by the description of those uses. The Commission concurs with SEAC's conclusion.

(19) In order to ensure that the authorisation covers only those uses for which no suitable alternatives are available, it is necessary to further specify the description of uses 2, 4 and 5 by aligning it with the conclusions of the analysis of alternatives as presented in the application and as assessed by SEAC. The Commission considers that the applicants [for authorisation] have discharged their burden of proof in demonstrating the absence of suitable alternatives as regards uses 2, 4 and 5, only with regard to such limited scope of the uses.

(20) Therefore, the description of uses 2, 4 and 5 should be further specified by referring to uses where any of the following key functionalities is necessary for the intended use …

…

(22) In addition, the Commission took note of the complexity of the supply chains concerned by the uses applied for, the time and investment necessary to implement a potential alternative, as well as the time necessary for its industrialisation and for the qualification of the resulting products in the supply chains. The Commission, having evaluated SEAC's assessment, and taking the above considerations into account, agrees with the conclusion that there are no suitable alternative substances or technologies for uses 2, 4 and 5.'

27 In addition, recitals 26 and 27 read as follows:

‘(26) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC, and based its conclusions on the existence of a sufficient weight of evidence allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional exposure and emission information.

(27) Furthermore, in order to facilitate the enforcement of this Decision, with regard to uses 2, 4 and 5, it is necessary to require the authorisation holders’ downstream users to include in the notification sent to the Agency pursuant to Article 66(1) of Regulation (EC) No 1907/2006, an explanation of the key functionalities listed in Article 1(1) of this Decision which are necessary for their use, including a justification why they are necessary for that use …’

28 Article 1(1) of the contested decision grants authorisation for the five categories of uses of chromium trioxide applied for, within the limits set out therein:

– use category 1, consisting of the formulation of mixtures for uses 2, 4, 5 and 6;

– use category 2, consisting of functional chrome plating where any of the following key functionalities is necessary for the intended use: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, or effect on surface morphology;

– use category 4, consisting of surface treatment for applications in the aeronautics and aerospace industries, unrelated to functional chrome plating or functional chrome plating with decorative character, where any of the following key functionalities is necessary for the intended use: corrosion resistance/active corrosion inhibition, chemical resistance, hardness, adhesion promotion (adhesion to subsequent coating or paint), temperature resistance, resistance to embrittlement, wear resistance, surface properties impeding deposition of organisms, layer thickness, flexibility, and resistivity;

– use category 5, consisting of surface treatment (except passivation of tin-plated steel (electrolytic tin – ETP)) for applications in architectural, automotive, metal manufacturing and finishing, and general engineering industry sectors, unrelated to functional chrome plating or functional chrome plating with decorative character, where any of the following key functionalities is necessary for the intended use: corrosion resistance, active corrosion inhibition, layer thickness, humidity resistance, adhesion promotion (adhesion to subsequent coating or paint), resistivity, chemical resistance, wear resistance, electrical conductivity, compatibility with substrate, (thermo) optical properties (visual appearance), heat resistance, food safety, coating tension, electric insulation or deposition speed;

– use category 6, consisting of passivation of tin-plated steel (electrolytic tin plating – ETP).

29 According to Article 2(2) of that decision:

‘The authorisation holders shall develop specific exposure scenarios for representative processes, operations and individual tasks (including automatic versus manual systems and open versus closed systems and combinations thereof), describing risk management measures and operational conditions to control worker exposure to chromium (VI) and its emissions into the environment,

representative for all sites at which the authorised uses take place, in each of the specific scenarios. The exposure scenarios shall contain information on the exposure levels resulting from the implementation of those risk management measures and operational conditions.

The authorisation holders shall select the risk management measures described in the specific exposure scenarios in accordance with Article 5 of Directive 2004/37/EC [of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ 2004 L 158, p. 50)]. The authorisation holders shall document and justify the selection of risk management measures and shall make available the relevant documents to the competent authorities of the Member State where an authorised use takes place upon request.'

30 Article 5 of the contested decision establishes that, as regards authorisation for use categories 2, 4 and 5, 'the downstream users shall include in the notification to the Agency pursuant to Article 66(1) of [the REACH Regulation] an explanation of the key functionalities of chromium trioxide listed in Article 1(1) which are necessary for their use, including a justification why such key functionalities are necessary for that use.'

Forms of order sought and procedure before the Court

31 The Parliament claims that the Court should:

– annul Article 1(1) and (5) and Articles 2 to 5, 7, 9 and 10 of the contested decision, inasmuch as they concern authorisations for uses 2, 4 and 5, as well as use 1 in relation to the formulation of mixtures for uses 2, 4 and 5;

– in the alternative, annul the contested decision; and

– order the Commission to pay the costs.

32 The Commission contends that the Court should:

– dismiss the claim for partial annulment of the contested decision;

– in the alternative, dismiss the claim for annulment of the contested decision in its entirety;

– in the event of annulment by the Court of the contested decision, order that its effects be maintained; and

– order the Parliament to pay the costs.

33 By document lodged at the Court Registry on 27 May 2021, the European Chemicals Agency (ECHA) applied, on the basis of the second paragraph of Article 40 of the Statute of the Court of Justice of the European Union and Article 130 of the Rules of Procedure of the Court of Justice, for leave to intervene in the present case in support of the form of order sought by the Commission. By order of 17 September 2021, the President of the Court granted that request.

34 ECHA has submitted a statement in intervention in support of the form of order sought by the Commission.

The claims for annulment

Admissibility of the claim for partial annulment

35 As its principal claim, the Parliament asks the Court to annul Article 1(1) and (5) and Articles 2 to 5, 7, 9 and 10 of the contested decision, inasmuch as they concern authorisations for uses 2, 4 and 5, as well as use 1 in relation to the formulation of mixtures for uses 2, 4 and 5.

36 It is clear from the settled case-law of the Court that the partial annulment of an EU act is possible only if the elements for which annulment is sought can be severed from the remainder of the act. In that regard, the Court has repeatedly held that the requirement of severability is not satisfied in the case where the partial annulment of an act would have the effect of altering the substance of the part of that act that has not been annulled (see, to that effect, judgment of 9 November 2017, *SolarWorld* v *Council*, C-205/16 P, EU:C:2017:840, paragraph 38 and the case-law cited).

37 In the present case, the contested decision is made up of a collection of authorisations relating to separate uses of chromium trioxide and the principal claim submitted by the Parliament seeks annulment of the contested decision only inasmuch as it relates to authorisations for uses 2, 4 and 5, as well as use 1 in relation to the formulation of mixtures for those uses.

38 Consequently, any annulment of the authorisation granted by the contested decision for those uses would not affect the authorisation granted for the other uses and would therefore not alter the substance of the part of that decision not annulled.

39 In those circumstances, the principal claim submitted by the Parliament, seeking the partial annulment of the contested decision, concerns elements which are severable from the remainder of that decision and is, therefore, admissible.

Substance

Preliminary observations

40 It should be recalled that the authorisation of a substance included in Annex XIV to the REACH Regulation, such as chromium trioxide, may be granted in two situations, namely:

– pursuant to Article 60(2) of the REACH Regulation, when the risk to human health or the environment from its use is adequately controlled; or

– failing that, under Article 60(4) of that regulation, 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.

41 In the present case, the Commission considered that the risk to human health of the proposed uses of chromium trioxide was not adequately controlled and therefore relied on Article 60(4) of the REACH Regulation to authorise, by the contested decision, certain uses of that substance.

42 In support of its action, the Parliament raises a single plea in law, alleging that the Commission did not sufficiently ascertain that the conditions laid down in Article 60(4) and (7) of the REACH Regulation had been satisfied.

43 In that regard, the Court has held, in the first place, that it follows from Article 60(4) of the REACH Regulation, read in conjunction with recital 69 thereof, that it is for the applicant for authorisation to establish that the conditions laid down in that article for the grant of authorisation are satisfied (see, to that effect, judgment of 25 February 2021, *Commission* v *Sweden*, C-389/19 P, EU:C:2021:131, paragraph 33).

44 Article 62(4) of the REACH Regulation specifies the information that the applicant for authorisation must provide when submitting its application for authorisation. Thus, under point (d) of that provision, that application must be accompanied by a chemical safety report, drawn up in accordance with Annex I to that regulation, that addresses the risks to human health or the environment from the use of the substance at issue arising from its intrinsic properties as described in Annex XIV to that regulation.

45 Under point 5.2.4 of Annex I to the REACH Regulation, the estimation of the exposure levels for all human populations (workers, consumers and persons exposed indirectly via the environment) made in the chemical safety report is to take into account, in particular, 'adequately measured, representative exposure data'.

46 In the second place, the Court has also held 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. If, after its examination and in the light of all the evidence provided by the applicant for authorisation and by other persons or gathered by itself, the Commission is of the view that the applicant for authorisation fails to adduce the evidence which the burden of proof on that applicant requires, that institution must refuse the authorisation requested (see, to that effect, judgment of 25 February 2021, *Commission* v *Sweden*, C-389/19 P, EU:C:2021:131, paragraph 33).

47 The Commission is assisted in the exercise of that power by ECHA, whose two committees – RAC and SEAC – are, under Article 64 of the REACH Regulation, each to deliver an opinion on the application for authorisation.

48 Thus, as regards RAC, Article 64(4)(a) of that regulation provides that it is to assess '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, [undertake] an assessment of the risks arising from possible alternatives'. SEAC, for its part, must carry out, pursuant to Article 64(4)(b) of that regulation, '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'.

The first part of the single plea in law

– *Arguments of the parties*

49 By the first part of its single plea in law, the Parliament submits that the Commission infringed Article 60(4) of the REACH Regulation by authorising uses of a substance of very high concern, namely chromium trioxide, without first having made a conclusive assessment of the risk to human health arising from those uses. In those circumstances, the Commission was not in a position to ensure that 'socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance', as is required by that provision.

50 The Parliament notes that Article 62(4)(d) of the REACH Regulation requires an application for authorisation to include '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)', and that point 5.2.4 of that annex provides that the exposure estimation is to take into account, inter alia, 'adequately measured, representative exposure data'.

51 According to the Parliament, it is apparent from RAC's opinions, the conclusions of which are set out in recitals 10 and 11 of the contested decision, that the information provided by the applicants for authorisation for uses 1, 2, 4 and 5 is unrepresentative, given the small amount of exposure data measured, and of questionable reliability, particularly as regards worker exposure, given the lack of sufficient information on operational conditions, risk management measures and exposure levels for specific tasks and sites.

52 Moreover, as is apparent from recital 12 of the contested decision, the Commission decided, on RAC's express recommendation, to impose additional conditions and monitoring arrangements. Thus, Article 2(2) of the contested decision made the granting of authorisations subject to the condition that their holders provide, in the review report, essential data, such as exposure scenarios and related risk management measures, which are lacking in the risk assessment. Such a condition demonstrates that the Commission could not reliably and conclusively determine whether 'socio-economic benefits outweigh the risks to human health or the environment arising from the use of the substance'.

53 In its defence, the Commission contends that any scientific assessment inherently involves uncertainties. Despite the uncertainties mentioned by the Parliament, as already noted in the RAC opinion and also fully acknowledged in the recitals of the contested decision, the Commission considers that the applicants for authorisation discharged their burden of proof. It considers that it was in a position to conclude that the socio-economic benefits outweighed the risks to human health.

54 As regards the uncertainties concerning worker exposure, the Commission observes, in the first place, that, despite the limited availability of measured exposure data in the chemical safety report, RAC considered that the data provided were sufficient to carry out the assessment and to allow SEAC to weigh the benefits against the risks, as noted in recital 10 of the contested decision.

55 In the second place, it could not be expected of the applicants for authorisation to provide measured exposure data from over 1 500 downstream users' sites, since the number of those sites could not be known at the time the authorisation was granted.

56 In the third place, the fact that the relevant exposure levels of 2 μg/m^3, for use categories 2, 4 and 5, and 0.5 μg/m^3, for use category 1, represent, respectively, one fifth and one twentieth of the binding EU occupational exposure values for chromium (VI) compounds, applied in accordance with Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ 2017 L 345, p. 87), shows that the contested decision contributes to reducing exposure by improving the protection of workers and is therefore consistent with the aims of the authorisation.

57 In the fourth place, RAC also recommended additional conditions and monitoring arrangements that were reflected in the contested decision, the aim of which is to reduce workplace exposure further.

58 In the light of the uncertainties identified by RAC and in order to test the robustness of the risk/benefit ratio, SEAC, as the Commission explained in recital 15 of the contested decision, relied on the worst-case scenario, from which it deduced that the benefits of continuing to use chromium trioxide outweighed the risks to human health.

59 The Commission thoroughly reviewed the RAC and SEAC opinions and found them full, consistent and relevant. Contrary to the Parliament's assertion, the monitoring requirements set out in Article 2(2) of the contested decision are not aimed at remedying 'shortcomings in the application', but are intended to secure the generation of additional exposure and emission information, in accordance with the recommendations made in the ECHA opinions. This is also consistent with the overall logic of the REACH Regulation, which is based on a principle of continuous improvement and specifically aims to improve the quality of chemicals regulation over time through the continuous generation and improvement of data on substances for regulatory purposes.

60 In its statement in intervention submitted in support of the form of order sought by the Commission, ECHA contends that SEAC took into account the remaining uncertainties concerning the exposure of workers by opting for the worst-case scenario, with the result that those uncertainties do not call into question that committee's conclusion that the socio-economic benefits of the authorised uses outweigh the risks to human health.

– *Findings of the Court*

61 By the first part of the single plea in law, the Parliament criticises the Commission for having considered that the socio-economic benefits of uses 1, 2, 4 and 5 of chromium trioxide which it authorised outweigh the risks to human health arising from those uses, even though it had failed to come, prior to its assessment, to a sound and conclusive judgment on those risks.

62 In the first place, RAC emphasised in its opinions, as is apparent from recital 10 of the contested decision, the unreliability of worker exposure data for all the uses at issue, referring to 'a prevalent lack of contextual information' on the conditions under which they were measured.

63 In particular, in its opinion concerning use category 2 (functional chrome plating), RAC described this problem in the following terms: 'the greatest uncertainty arises from the lack of clear link between the [operating conditions], [risk management measures] and exposure values for specific tasks and sites, which could justifiably represent the application. RAC sees this as a substantial weakness of the application, considering that there is a wide variability between the

chromium plating sites in relation to e.g. building layout, the scale and frequency of plating operations, level of the automation of the process, use of electrolysis, the size of the parts treated, and the availability of [local exhaust ventilation], which affects the exposures and [risk management measures] needed to control the exposure'.

64 In the second place, and as the Commission itself acknowledged in recital 10 of the contested decision, RAC identified in its opinions significant uncertainties concerning worker exposure due to the limited availability of measured exposure data.

65 Thus, while the number of potential sites in the European Union performing functional chrome plating (use category 2) was estimated by the applicants for authorisation to be 1 590, the latter based their assessment of worker exposure on the measured data from 23 companies established in 7 different States, representing less than 2% of the companies involved in that use. Similarly, while the number of potential sites in the European Union carrying out surface treatments (use categories 4 and 5) was estimated by the applicants for authorisation to be 374 and 515, respectively, the latter based their assessment of worker exposure on data measured by 11 undertakings representing less than 3% of companies having recourse to those uses and from studies mainly carried out in western European countries.

66 It should therefore be noted that, given the wide variability between the chrome plating sites in several decisive respects, referred to in paragraph 63 above, the small number of chrome plating sites from which the data underpinning the assessment of the applicants for authorisation came and the lack of contextual information on the conditions prevailing in those sites, the worker exposure data provided by the applicants for authorisation are not representative.

67 In the third place, as regards the risk assessment arising from the exposure of the general population due to the release of the substance into the environment, RAC expressed its disappointment that the applicants for authorisation had not provided an assessment of release of the substance into wastewater. However, as is stated in recital 11 of the contested decision, that committee did not consider that deficiency to be conclusive, on the twofold ground that the assumptions made by the applicants for authorisation likely overestimated the risks to the general population and that chromium (VI) rapidly transforms into non-carcinogenic chromium (III) under most environmental conditions.

68 It follows from the foregoing that the data submitted by the applicants for authorisation concerning exposure to chromium trioxide of workers and the general population on account of the uses for which authorisation was sought were vitiated by a lack of representativeness, reliability and completeness. Moreover, in recitals 10 to 12 of the contested decision, the Commission itself acknowledged that the assessment of that exposure to chromium trioxide was affected by uncertainties.

69 Admittedly, as the Commission rightly points out, any scientific assessment inherently involves uncertainties, meaning that authorisation cannot be made conditional on its succeeding in eliminating them completely.

70 However, the Commission may grant an authorisation applied for under Article 60(4) of the REACH Regulation only where the conditions set out in that provision are in fact satisfied and where it considers, after having carried out a detailed examination and verified a sufficient

amount of material and reliable information, that the remaining uncertainties are negligible (see, to that effect, judgment of 25 February 2021, *Commission* v *Sweden*, C-389/19 P, EU:C:2021:131, paragraphs 33 and 35).

71 In the present case, as the Advocate General observed in point 124 of his Opinion, the uncertainties relating to both worker exposure and the indirect exposure of the population as a result of the release of chromium trioxide into the environment were not classified as 'negligible' either in the contested decision or in the RAC opinions. On the contrary, in recital 10 of that decision, the Commission itself described the uncertainties concerning workers' exposure as 'significant'. As was also observed by the Advocate General in point 119 of his Opinion, RAC even considered the absence of a clear link between the operational conditions (which vary depending on the task and the site), risk management measures and reported exposure values to be 'the greatest uncertainty', vitiating the application with a 'substantial weakness' as regards the four use categories concerned.

72 Furthermore, it should be borne in mind that chromium trioxide is among the 'substances of very high concern' which, according to recital 69 of the REACH Regulation, should, in accordance with the precautionary principle, be subject to careful attention. As the Advocate General observed, in essence, in point 133 of his Opinion, an approach allowing uses of chromium trioxide to be authorised on the basis of a very limited quantity of data relating to those uses would be manifestly contrary to the objective of treating that substance with careful attention.

73 The Commission nevertheless disputes the significance of the uncertainties affecting the risk assessment, arguing, in the first place, that it could not be required of the applicants for authorisation to provide exposure data on all the sites concerned by the application for authorisation, given their very high number. By way of illustration, the Commission states that, as regards use category 2 (functional chrome plating), that number amounts to more than 1 500.

74 It is true, as the Commission notes, that the possibility for upstream actors, generally manufacturers or importers of substances, to apply for the whole supply chain has the advantage of streamlining the authorisation system, and that that advantage would be undermined if applicants for authorisation were required to provide data concerning all the sites of downstream users.

75 However, the fact remains that point 5.2.4 of Annex I to the REACH Regulation requires the applicant for authorisation to provide 'adequately measured, representative exposure data'.

76 In that connection, as regards the Commission's argument that the small number of sites assessed is justified by the very large number of sites for which authorisation was sought, it should be noted, as the Advocate General observed in point 134 of his Opinion, that the obligations arising from the burden of proof on the applicant for authorisation cannot depend on the number of uses for which authorisation is sought, or on the number of sites and undertakings potentially concerned. According to such an approach, the standard of risk assessment would be lower the broader the scope of the application, which would be contrary to both the principle of equal treatment of applicants for authorisation and the objective of protecting human health and the environment.

77 In the second place, the Commission contends that, in any event, the contested decision contributes to reducing exposure to chromium trioxide by improving worker protection. The relevant user exposure values are 2 μg/m^3 for categories 2, 4 and 5, and 0.5 μg/m^3 for category 1, which represents, respectively, one fifth and one twentieth of the binding EU occupational exposure values for chromium (VI) compounds currently applied under the legislation in force.

78 However, RAC stated in its opinions that the exposure value of 2 μg/m^3 was only an estimate made by the applicants for authorisation, that the available data showed variations in exposure, including by an order of magnitude greater than 2 μg/m^3, and that it 'clearly [did] not endorse exposures of 2 μg/m^3 Cr(VI) as proposed by the applicants [for authorisation] as being safe'.

79 In any event, the fact that worker exposure values are lower than the maximum exposure values for chromium (VI), assuming it were established, would not be such as to exempt the applicants for authorisation from carrying out a risk assessment in conformity with the requirements of Article 60(4) of the REACH Regulation, read in conjunction with, inter alia, point 5.2.4 of Annex I to that regulation, on the basis of reliable and representative data.

80 In the third place, the Commission states that it took into account the uncertainties of the risk assessment by laying down, on RAC's recommendation, additional conditions and monitoring arrangements in order further to reduce workers' exposure to chromium trioxide.

81 In that regard, it is true that Article 2 of the contested decision lays down a series of obligations on the authorisation holders and the downstream users. The authorisation holders must develop specific exposure scenarios for representative processes, operations and individual tasks (paragraph 2); they must make available the specific exposure scenarios to the downstream users, who are required to apply the risk management measures and operating conditions included in those scenarios without undue delay (paragraph 3); they must verify and validate the specific exposure scenarios by making an analysis of the tasks, using exposure and emission data measured by downstream users (paragraph 4). The authorisation holders and the downstream users must implement monitoring programmes that are representative of operational conditions and risk management measures (paragraph 6). The downstream users must make available to ECHA the information collected through those monitoring programmes, for transmission of that information to the authorisation holders for the purpose of verifying and validating the exposure scenarios (paragraph 9).

82 However, as is apparent from the case-law cited in paragraph 70 of the present judgment, the Commission must verify that the conditions set out in Article 60(4) of the REACH Regulation are in fact satisfied before granting an authorisation under that provision.

83 Although the additional conditions and monitoring arrangements laid down by the Commission in Article 2(2) of the contested decision may, as the case may be, reduce the exposure to risk of users of chromium trioxide, such measures are not, however, capable of remedying the insufficiency of the risk assessment at the date of adoption of that decision.

84 It follows from all the foregoing that, by the contested decision, the Commission authorised uses of chromium trioxide on the basis of an assessment of their risks to human health that had too many shortcomings to satisfy the requirements of Article 60(4) of the REACH Regulation.

85 Accordingly, the Parliament is justified in arguing that the Commission was not in a position to conclude that the socio-economic benefits of those uses outweigh the risks they entail for human health.

86 The first part of the single plea in law must therefore be upheld.

The second part of the single plea in law

– *Arguments of the parties*

87 By the second part of its single plea in law, the Parliament submits that the Commission failed to fulfil its obligation to ascertain that there was no suitable alternative for authorised use categories 2, 4 and 5, as is required by Article 60(4) of the REACH Regulation.

88 As is apparent from recital 18 of the contested decision, the Commission itself agreed with SEAC's conclusion relating to use categories 2, 4 and 5 that, due to the very broad scope of the uses in the application, that committee could not exclude possible uncertainty with regard to the technical feasibility of alternatives for a limited number of specific applications.

89 It is true that, in order to ensure that the authorisation covers only uses for which no suitable alternative is available, the Commission decided to restrict the scope of the authorisation for categories 2, 4 and 5 by inserting a reference to the 'key functionalities necessary for the intended use', as is apparent from recitals 19 and 20 of the contested decision. Thus, that decision establishes a list of key functionalities for each of those three use categories and authorises the use of the substance only if, and to the extent that, at least one of the corresponding key functionalities is necessary for that use.

90 The Commission then considered that the applicants for authorisation had discharged the burden of proof by demonstrating that there were no suitable alternatives for use categories 2, 4 and 5, only within those limits.

91 However, according to the Parliament, the reference to those 'key functionalities necessary for the intended use' was not such as to remedy the uncertainty identified by the Commission itself. Moreover, the General Court has expressly held that the possibility of attaching certain conditions to an authorisation, such as those laid down in Article 60(8) and (9)(d) of the REACH Regulation, does not allow the Commission to remedy deficiencies in the analysis of alternatives submitted by applicants for authorisation or deficiencies or shortcomings in the Commission's assessment (see, to that effect, judgment of 7 March 2019, *Sweden* v *Commission*, T-837/16, EU:T:2019:144, paragraphs 81 to 83).

92 In addition, according to the Parliament, the Commission itself failed to ascertain the lack of availability of suitable alternatives, as is confirmed by recital 27 and Article 5 of the contested decision. That article requires downstream users to include in the notification sent to ECHA, pursuant to Article 66(1) of the REACH Regulation, an explanation of the key functionalities listed in Article 1(1) of the contested decision that are necessary for their use, including a justification of why they are necessary for that use.

93 That information requirement demonstrates that, even within the limits of the authorisation supposedly restricted by the requirement relating to 'key functionalities necessary for the intended use', there is uncertainty as regards the absence of suitable alternatives for use categories 2, 4 and 5. Article 1(1) of the contested decision, read in the light of Article 5 thereof, confers on downstream users the task of explaining the key functionalities listed in that decision and justifying why any of those functionalities is indeed necessary for the intended uses.

94 Furthermore, according to the Parliament, the insertion of the reference to the 'key functionalities' does not amount to a genuine restriction of the scope of the authorisation. Since the Commission did not establish in the contested decision when and under what circumstances those 'key functionalities' are necessary for the uses at issue, that reference merely recalls one of the general requirements of Article 60(4) of the REACH Regulation, namely that the substance may be authorised only if it is necessary for the intended use. That restriction is all the more pointless since the 'key functionalities' listed in Article 1(1) of the contested decision are in fact all the functionalities of chromium trioxide for use categories 2, 4 and 5.

95 In its defence, the Commission contends that it did fulfil its obligation to ascertain that no suitable alternatives were available for the uses authorised, as is required by Article 60(4) of the REACH Regulation.

96 The Commission explains that, although it was able to make a reliable finding that there was no suitable alternative for all category 2, 4 and 5 uses, as defined in the application, the same cannot be said for each downstream use covered by the application. That is why it listed the 'key functionalities' of the substance that no alternative could viably provide and authorised only those uses for which those 'key functionalities' were necessary.

97 Thus, according to the Commission, the contested decision is limited by objective criteria – such as corrosion resistance, adhesion and food safety – that allow its scope to be determined. By no means do downstream users or competent authorities need to perform a new assessment of the substance or of the alternatives or make any comparison of them. The necessity of the substance for all types of downstream use is established by the contested decision.

98 Hence, the contested decision constitutes only a partial authorisation of the uses of chromium trioxide for which authorisation was applied for, as is clear from Article 1(2) to (4) thereof. All downstream users purporting to be using the substance under the authorisation must report the uses they make of it under the authorisation to ECHA, indicate which key functionality or functionalities of the substance is of technical necessity for their activities, and explain why. The competent authorities, which have access to the ECHA register of downstream users, are obliged by the REACH Regulation to ensure it is correctly implemented and enforced.

99 The Commission states that it did not carry out a separate assessment of the alternatives for each downstream user or product, since that task would have meant thousands or possibly millions of separate assessments, depending on the level of specificity, which the REACH Regulation in no way requires, even implicitly.

100 Moreover, if the Court were to require a more detailed and specific assessment of the downstream uses covered by an application for authorisation than is currently conducted, the entire application and assessment process would become much more complex than it is already. That requirement would run counter to the REACH Regulation's objective to promote the competitiveness of EU industry, taking special account of the potential impact on SMEs, as

recital 8 of the REACH Regulation recalls. It would also fail to have regard to the fact that that regulation also has as its objective, as is stated in Article 55 thereof, the progressive replacement of substances of very high concern by alternative substances, as well as the constant new inclusion of substances in the authorisation system and the refinement of regulatory measures over time, including through regular reviews of authorisations granted.

101 In addition, a more demanding regime for assessing alternatives would exceed the administrative capacities of ECHA and make it necessary to limit the number of substances subject to authorisation. Moreover, Article 58(3) of the REACH Regulation provides explicitly that 'the number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for'. Multiplying assessments of alternatives would have the effect of stalling the identification of new substances of very high concern, resulting in the hyper-regulation of only a small number of substances. This would result in some substances being substituted by less regulated, less well-known alternative substances for which there is less data, and would speed up the substitution of substances of very high concern included in Annex XIV to the REACH Regulation only.

102 Lastly, the Commission notes that the regulation should not be interpreted statically. In line with the principle of progressivity, the Commission's discretionary assessment should become more demanding over time. The approach to the assessment of applications for authorisation implemented by the Commission and ECHA is a result of years of experience in managing the authorisation system and is based on a highly delicate balancing of scientific and socio-economic considerations and on the multiple objectives pursued by the REACH Regulation, always with a primary focus on the objective of safeguarding human health and the environment.

103 In its statement in intervention, ECHA points out that the Commission did not rely on any subjective assessment by downstream users as regards the lack of an appropriate alternative; downstream users are required only to provide supervisory authorities with information demonstrating that, due to objective technical requirements or regulatory standards, the use of chromium trioxide is necessary.

– *Findings of the Court*

104 By the second part of the single plea in law, the Parliament submits that the Commission failed to fulfil its obligation to ascertain that the second condition laid down in Article 60(4) of the REACH Regulation was satisfied for use categories 2, 4 and 5, that is to say, that there was no suitable alternative for those uses.

105 In that regard, it is apparent from recital 12 of the REACH Regulation that that condition meets an important objective of the system established by that regulation, which is to encourage – and, in certain cases, ensure – that substances of very high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available.

106 As has been recalled in paragraph 46 above, Article 60(4) and (5) of the REACH Regulation requires the Commission to verify that that condition, like the first condition laid down in Article 60(4) of that regulation, is in fact satisfied.

107 It should also be borne in mind that the Commission is assisted to that end by ECHA and, in particular, by SEAC, which must issue an opinion on, inter alia, the availability, suitability and technical feasibility of alternatives.

108 In the present case, SEAC issued, with regard to use category 2 and, in almost identical terms, use categories 4 and 5, the following assessment:

'The [applicants for authorisation have] made an extensive assessment of alternatives, especially when it comes to the aspect of technical feasibility.

…

Nevertheless, due to the extremely broad scope of this use applied for, SEAC cannot exclude that there are indeed a limited number of applications where substitution is already feasible or will become so at short-term. In fact, it is not clear to SEAC when alternatives will eventually become available for specific applications. Ideally, SEAC would have been provided with an exhaustive list of all the applications/components covered by [the use in question] in order to judge the actual feasibility/infeasibility of alternatives and to ensure that substitution takes place where already feasible. However, SEAC recognises that this is hardly possible for applications for authorisation covering such a broad scope and hence [including] such a high number of products. The [applicants for authorisation have] provided a list containing an overview of sectors concerned, respective article examples and [the analysis of the question as to] whether or not alternative technologies claimed feasible by third parties can be applied or not. Due to the broad scope of the use applied for and the fact that numerous applications are covered by this use, this list cannot be considered exhaustive. According to the [applicants for authorisation], applications where substitution is already possible are not covered by the application anyhow. The [applicants for authorisation], however, [do] not specify such applications or their related technical requirements. SEAC finds the … approach [of the applicants for authorisation] to resolve this issue not fully appropriate and emphasises the need for the [applicants for authorisation] to demonstrate more concretely that substitution has taken place where indeed already feasible. This could have been achieved by undertaking a more precise and use-specific assessment of alternatives. Generally, it should be made clear by [the applicants for authorisation] which technical applications are covered by the use applied for and which are not.

However, based on the available information, SEAC agrees to the … conclusion [of the applicants for authorisation] that *overall*, technically feasible alternatives for chromium trioxide [in the corresponding use] do not seem to exist before the sunset date. The uncertainties pointed out above are taken into account by SEAC in the recommendation for the review period and the condition for the review report.'

109 In recital 18 of the contested decision, the Commission adopted SEAC's opinion on this point in the following terms:

'In its opinions on uses 2, 4 and 5, SEAC concluded that there are no suitable alternative substances or technologies. However, due to the very broad scope of the uses applied for, SEAC could not exclude possible uncertainty with regard to the technical feasibility of alternatives for a limited number of specific applications that are covered by the description of those uses. The Commission concurs with SEAC's conclusion.'

110 Thus, the Commission accepted, endorsing the conclusions in the SEAC opinion, that uncertainties remained as to the existence of suitable alternative substances or technologies for certain applications coming within the scope of the uses for which authorisation was sought.

111 As is apparent from recital 19 of the contested decision, the Commission required that the description of uses 2, 4 and 5 be specified further in order to ensure that the authorisation covers only uses for which no suitable alternatives are available.

112 That is why the Commission decided, as it stated in recital 20 of that decision, to limit the scope of the authorisation to the uses for which the 'key functionalities' of chromium trioxide are necessary, those functionalities being, for example, for functional chrome plating (category 2), wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction and effect on surface morphology.

113 However, the limitation of the scope of the authorisation by reference to the 'key functionalities' of chromium trioxide is not such as to ensure compliance with the second condition laid down in Article 60(4) of the REACH Regulation.

114 In the first place, as the Advocate General observed in point 178 of his Opinion, it is not possible to conclude from the fact that one of the 'key functionalities' identified in the contested decision is necessary for a given use that there are no suitable alternative substances or technologies for that use. Thus, the limitation of the authorisation of the use of chromium trioxide to the uses for which the key functionalities of that substance are necessary is not capable of remedying the uncertainties relating to the absence of alternatives for certain uses.

115 In the second place, the reference to the 'key functionalities' necessary for the intended use, listed in Article 1(1) of the contested decision, does not actually limit the scope of the authorisation granted.

116 First, as the Parliament maintains in its written pleadings without being contradicted in that regard, the 'key functionalities' listed appear in reality to cover all the functionalities of chromium trioxide for use categories 2, 4 and 5.

117 Second, the concept of 'key functionality' has no objective content, since the level of performance required for such a functionality is not specified. Thus, the reference to 'hardness' as a key functionality has no useful purpose since the degree of hardness required is not specified. Similarly, the reference to 'corrosion resistance' cannot have the effect of limiting the authorisation of the use, since the duration of that resistance and the conditions under which it is required are not specified, either.

118 In those circumstances, the limitation of the scope of the authorisation that the reference to the 'key functionalities' of chromium trioxide is supposed to entail is not a true limitation, since it merely recalls one of the conditions for the authorisation of a substance of very high concern, namely that that substance must be necessary for the intended use (see, to that effect, judgment of 25 February 2021, *Commission* v *Sweden*, C-389/19 P, EU:C:2021:131, paragraph 44).

119 In the third place, in view of the vagueness of the concept of 'key functionality', the resulting limitations of the authorisation may, in any event, be difficult to monitor effectively.

120 That finding is supported by the obligation imposed on downstream users by Article 5 of the contested decision to provide ECHA with an explanation of the key functionalities of chromium trioxide which are necessary for their intended use, including a justification of why those essential functionalities are necessary for that use.

121 It is true that recital 82 of the REACH regulation states that, 'to allow effective monitoring and enforcement of the authorisation requirement, downstream users benefiting from an authorisation granted to their supplier should inform the Agency of their use of the substance'.

122 However, in the present case, the obligation set out in Article 5 of the contested decision amounts, first, to requiring downstream users to provide additional information for the purpose of assessing the condition that there are no alternatives for the uses under consideration, after those uses have been authorised by the Commission. Second, since the contested decision does not adequately set out, as has been stated in paragraph 117 of this judgment, the content of the 'key functionalities', the responsibility for determining whether the use of chromium trioxide is necessary to achieve the required level of performance is de facto transferred to downstream users, who have full discretion to determine the level of performance required and, therefore, whether or not alternatives exist.

123 As has been recalled in paragraphs 46 and 82 above, the verification that the conditions laid down in Article 60(4) of the REACH Regulation are satisfied, first, must take place before an authorisation is issued under that provision and, second, comes within the exclusive competence of the Commission.

124 It follows from the foregoing that the Commission was not in a position to conclude that there are no suitable alternatives for the uses of chromium trioxide which it authorised by the contested decision.

125 That conclusion cannot be called into question on the ground, first, that it reflects a degree of exigency that is incompatible with the REACH Regulation's objective to promote the competitiveness of EU industry and with ECHA's capacity to handle applications for authorisation in the time provided for.

126 As is apparent from recital 1 of the REACH Regulation, the objectives of that regulation are to ensure a high level of protection of human health and the environment and the free movement of substances on the internal market while enhancing competitiveness and innovation (judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 35). Moreover, as is apparent from recital 22 of that regulation, the authorisation provisions should ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. That is why considerations relating solely to the competitiveness of EU industry cannot justify authorising the use of a substance of very high concern for human health and the environment which is not strictly necessary.

127 Second, although the number of substances included in Annex XIV to the REACH Regulation must also take into account ECHA's capacity to handle applications in the time provided for, as Article 58(3) of that regulation expressly provides, that fact does not mean, as the Advocate General rightly observed in point 191 of his Opinion, that the assessments required by the authorisation procedure for a substance of very high concern can be carried out, on account of the limits to that capacity, less thoroughly than is required by the precautionary principle, to which Article 1(3) of that regulation refers.

128 The second part of the single plea in law must therefore also be upheld.

129 It follows that, by authorising uses 2, 4 and 5 of chromium trioxide, as well as use 1 in relation to the formulation of mixtures for uses 2, 4 and 5, the Commission failed to fulfil its obligation under Article 60(4) of the REACH Regulation.

130 The single plea in law must therefore be upheld, without there being any need to rule on the third part of that plea.

131 It follows from all the foregoing that Article 1(1) and (5) and Articles 2 to 5, 7, 9 and 10 of the contested decision must be annulled inasmuch as they concern the authorisations for uses 2, 4 and 5 of chromium trioxide, as well as use 1 in relation to the formulation of mixtures for uses 2, 4 and 5.

The claim seeking the provisional maintenance of the effects of the decision at issue

Arguments of the parties

132 The Commission requests, in the interest of protecting human health, that the effects of the contested decision be maintained until a new decision is adopted.

133 It states that Article 56(1)(d) of the REACH Regulation, read in conjunction with Article 58(1)(c) of that regulation, provides for a transitional mechanism allowing an applicant for authorisation and its downstream users to continue to place on the market and use a substance, even after the sunset date, where the use is covered by an application for authorisation, provided that that application was submitted at least 18 months before the sunset date and that the Commission has not yet taken a decision on the application for authorisation.

134 Consequently, according to the Commission, the annulment of the contested decision, if not accompanied by the maintenance of its effects, would have the effect of allowing the applicants for authorisation and their downstream users to continue to place on the market and use chromium trioxide for the uses applied for until the Commission adopts a new decision, without being subject to the various risk management and monitoring measures laid down in the contested decision which were specifically intended to protect human health.

135 The Parliament does not object to the Commission's request.

Findings of the Court

136 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 (judgment of 25 February 2021, *Commission* v *Sweden*, C-389/19 P, EU:C:2021:131, paragraph 72 and the case-law cited).

137 It should be noted, as a preliminary point, that the request for the provisional maintenance of the effects of the contested decision can concern only the provisions referred to in paragraph 138 above inasmuch as they concern the authorisations for uses 2, 4 and 5, as well as use 1 in relation to the formulation of mixtures for uses 2, 4 and 5.

138 As is apparent from paragraphs 84 and 124 above, the Commission, first, authorised uses of chromium trioxide on the basis of an assessment of their risks to human health which were too deficient to satisfy the requirements of Article 60(4) of the REACH Regulation and, second, was not in a position to conclude that there are no suitable alternatives for the uses of chromium trioxide that it authorised, such that the Commission should have rejected the application.

139 However, the fact remains that a period of time will necessarily elapse between the date of delivery of the present judgment and the rejection decision adopted by that institution. As the Commission states, according to Article 56(1)(d) of the REACH Regulation, a manufacturer, importer or downstream user is not to place a substance on the market for a use or use it himself if that substance is included in Annex XIV, 'unless … 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'.

140 Article 56(1)(d) thus refers to the two dates referred to in Article 58(1)(c)(i) and (ii) of the REACH Regulation, which concern, respectively, the 'sunset date', namely the date from which the placing on the market and use of the substance are to be prohibited, unless an authorisation is granted, and a date at least 18 months before the sunset date, establishing the time limit within which applications for authorisation must be received when the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date. In the latter case, those continued uses are to be allowed after the sunset date until a decision on the application for authorisation is taken.

141 As regards the substance chromium trioxide, it is apparent from Annex XIV to the REACH Regulation that the deadline for submitting the application for authorisation was 21 March 2016, that is 18 months before the sunset date of 21 September 2017. In the present case, the applicants for authorisation lodged their application in 2015.

142 It follows that, during the period of time between the delivery of the present judgment and the Commission's decision drawing the appropriate conclusions from this judgment, the applicants for authorisation and the downstream users of chromium trioxide could use that substance without being subject to the various risk management and monitoring measures laid down in the contested decision. It therefore appears necessary, in the interest of protecting human health, to provide for the provisional maintenance of the effects of the contested decision.

143 Nevertheless, in view of the uncertainties vitiating the scope of the contested decision, as noted in paragraph 124 of the present judgment, it cannot be ruled out that that decision authorises uses covered by the categories at issue for which there are suitable alternatives and that it thus exposes human health, in particular that of workers using chromium trioxide, to unjustified risks. In those circumstances, it is appropriate to provide for the effects of the contested decision to be maintained provisionally for a period not exceeding one year from the date of delivery of the present judgment.

Costs

144 Under Article 138(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

145 Since the Parliament has applied for costs and the Commission has been unsuccessful, the latter must be ordered to pay the costs.

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

1. **Annuls Article 1(1) and (5) and Articles 2 to 5, 7, 9 and 10 of Commission Implementing Decision C(2020) 8797 of 18 December 2020 partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Chemservice GmbH and others), inasmuch as those articles concern the authorisation for uses 2, 4 and 5, as well as use 1 in relation to the formulation of mixtures for uses 2, 4 and 5;**

2. **Declares that the effects of Implementing Decision C(2020) 8797 are to be maintained for a period not exceeding one year from the date of delivery of the present judgment;**

3. **Orders the European Commission to pay the costs.**

Lycourgos Rossi Bonichot

Rodin Spineanu-Matei

Delivered in open court in Luxembourg on 20 April 2023.

A. Calot Escobar C. Lycourgos
Registrar President of the Chamber