EUROPEAN
COMMISSION

Brussels, 29.7.2024
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COMMISSION IMPLEMENTING DECISION

of 29.7.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Liebherr-Aerospace Lindenberg GmbH for certain uses of chromium trioxide

(Only the English text is authentic)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 64(8) thereof,

Whereas:

(1) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 7 February 2022, Liebherr-Aerospace Lindenberg GmbH ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of chromium trioxide. The uses for which authorisation was sought are industrial use of chromium trioxide for functional chrome plating of actuation and landing gear systems for the aviation industry ('use 1'), and industrial use of chromium trioxide for surface treatment of aluminium alloys for applications in the aerospace industries unrelated to functional chrome plating ('use 2').

(3) The European Chemicals Agency sent the opinions on the application for authorisation for use 1[2] and use 2[3] adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 18 August 2023, the Commission received the opinions.

(4) In its opinions, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic and mutagenic properties of chromium trioxide in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide is a substance for which it is not possible to determine a

[1] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] https://echa.europa.eu/documents/10162/7be2ee22-e67e-ffaa-dfb6-3a40fbc4c98e

[3] https://echa.europa.eu/documents/10162/442fa881-c846-54c5-312c-4564e113e5ea

threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to chromium trioxide and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) In its opinion on use 1, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. Nevertheless, in order to further minimise the exposure of workers to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, RAC recommended imposing additional conditions for authorisation for use 1. Moreover, RAC recommended imposing additional monitoring arrangements for both occupational exposure to and environmental release of Cr(VI) for use 1, with the aim to address some minor shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period.

(6) In its opinion on use 2, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk to human health posed by the use of chromium trioxide described in the application. In particular, RAC noted that the measures in place are not in line with the principles of hierarchy of control and that further minimisation of occupational exposure can be achieved and, consequently, recommended additional conditions for authorisation. Moreover, RAC recommended monitoring arrangements for both occupational exposure to and environmental release of Cr(VI) for use 2, with the aim to address some minor shortcomings in exposure estimates and to provide information on the trends in exposure and emissions during the authorisation period.

(7) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that the estimated excess cancer risk values for workers as regards uses 1 and 2 are higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. Although the Commission acknowledges that those values are conservative estimates of the most likely excess risk values taken for the purpose of carrying out a risk-benefit analysis, it considers it appropriate to set out the measures concerning occupational exposure, recommended by RAC as monitoring arrangements, as a condition for authorisation.

(8) In its opinion on uses 1 and 2, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the uses of chromium trioxide. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the continued uses outweigh the risk to human health arising from those uses.

(9) For an alternative to be suitable it needs to be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

(10) An alternative that provides the functionality and level of technical performance necessary for the use for which an authorisation is sought should be considered to be technically feasible. Certain potential alternatives may provide the functionality, but at some loss of performance or in a manner that involves technical compromises that

would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses of performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(11) In its opinions on uses 1 and 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant but that there were technically and economically feasible alternatives in the Union at the time of adoption of the opinions. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that, although certain alternatives are already being used within the Union and by the applicant itself for some parts of the uses of chromium trioxide described in the application, they are not yet implemented for the whole scope of those uses. In fact, those alternatives do not allow meeting the high requirements needed by the applicant in the aerospace sector for all applications within the scope of the uses described in the application, including, among others, those related to the applicability to complex geometry parts, the sealing behaviour, the mating surfaces, a low coefficient of friction, the fatigue impact or the stand-alone process. Thus, the Commission acknowledges that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time for the development, qualification, and industrialisation processes of the alternatives. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicant.

(12) In its opinions on uses 1 and 2, SEAC concluded that the substitution plans submitted by the applicant are credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers, taking into account the availability of suitable alternatives in the Union for the uses for which authorisation is sought and the substitution plans submitted by the applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(13) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of chromium trioxide described in the application, provided that the risk management measures described in the chemical safety report are applied, and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.

(14) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require the authorisation holder to generate and include additional information about exposure and emissions in the review report.

(15) In its opinions on uses 1 and 2, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 12 years. As regards use 1, SEAC noted that the 14-year review period requested by the applicant was not warranted, taking into account that the applicant has overestimated the time

required for some phases of the substitution plans, and the excess lifetime cancer risk levels for workers and the local population as presented by the applicant and reviewed by RAC, but that only 12 years were warranted. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion on the appropriateness of the risk management measures and operational conditions, the excess cancer risk values for workers and the local population, SEAC's conclusions on the monetised risk to human health and on the socio-economic benefits of the continued uses of chromium trioxide, the lengthy qualification process to comply with the relevant aerospace and technical requirements, as well as the time needed for the modification of machinery and of the production plants.

(16) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member States where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(17) This Decision does not affect the obligation of the authorisation holder to ensure that the use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[4] to reduce the use of carcinogens, mutagens or reprotoxic substances at the place of work, in particular by replacing those substances, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or safety. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[5], 92/85/EEC[6], 94/33/EC[7], 98/24/EC[8] and Directive 2004/37/EC, or any

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4 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, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

5 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

6 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

7 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

8 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(18) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[9] or Directive 2010/75/EU[10] of the European Parliament and of the Council, nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(19) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 to the following person for the following uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/24/34/0	Liebherr-Aerospace Lindenberg GmbH	Industrial use for functional chrome plating of actuation and landing gear systems for the aviation industry
REACH/24/34/1		Industrial use for surface treatment of aluminium alloys for applications in the aerospace industries unrelated to functional chrome plating

[9] Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

[10] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

[11] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

[12] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety reports[13], and to the conditions set out in Articles 2 and 3.

Article 2

1. The authorisation bearing number REACH/24/34/0 is subject to the conditions set out in paragraphs 2 to 8.

2. The authorisation holder shall carry out by 29 July 2025, and afterwards each time when new relevant information becomes available, a study to assess the feasibility of implementing the following measures:

   (a) the substitution of solid chromium trioxide flakes with liquid chromium trioxide solutions or installation of a closed/automated system to perform the dissolution of solid chromium trioxide and any subsequent (re-)filling of the baths with liquid solutions;

   (b) the installation of an automated system to perform the bath adjustment;

   (c) the installation of a closed or automatic system to perform bath sampling tasks, where exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, is expected and where currently personal protective equipment is used to limit the risk for workers;

   (d) the installation of a system that continuously controls the local exhaust ventilation and automatically triggers an alarm in case the local exhaust ventilation is not functioning properly and the installation of appropriate and effective measures to reduce the exposure to workers in case the local exhaust ventilation is not functioning properly.

   The authorisation holder shall act in accordance with the outcome of that study.

3. The authorisation holder shall ensure that workers wear appropriate respiratory protection equipment during bath sampling, due to the potential for exposure to Cr(VI), until the task is performed with an automated system or closed sampling system.

4. The authorisation holder shall ensure that workers:

   (a) are provided with adequate respiratory equipment, which is subjected to a fit test prior to its first use;

   (b) always perform a fit check of the seal of their respiratory protective equipment before starting a relevant task;

   (c) are adequately supported to undergo the fit tests referred to in point (a) and trained to undertake the fit checks referred to in point (b).

5. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The programme shall include measurements which shall:

[13] https://ec.europa.eu/docsroom/documents/55694
https://ec.europa.eu/docsroom/documents/55695

(a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in exposure of workers to Cr(VI);

(b) be based on relevant standard methodologies or protocols;

(c) ensure a sufficiently low limit of quantification;

(d) comprise personal or static inhalation exposure sampling;

(e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, the operational conditions and risk management measures for each of those tasks, and of the total number of workers that are potentially exposed;

(f) be recorded so as to include contextual information about the tasks performed during exposure sampling.

6. The authorisation holder shall continue to conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

7. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 5 and 6 to review, at least annually, the appropriateness and effectiveness of risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of this review, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to Cr(VI). Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

8. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 5 and 6, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and studies and any measure taken in accordance with paragraphs 2 to 4 and 7, and shall make that information available, including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The authorisation bearing number REACH/24/34/1 is subject to the conditions set out in paragraphs 2 to 11.

2. The authorisation holder shall implement by 29 July 2025 technical improvements to the risk management measures and operational conditions implemented during all of the following tasks performed:

(a) at the manual plating lines;

(b) during weighing of solid chromium trioxide;

(c) during surface treatment of aluminium alloys by brushing or pen-stick.

3. The authorisation holder shall conduct control measurements to validate the appropriateness and effectiveness of the additional risk management measures and operational conditions implemented in accordance with paragraph 2. If necessary, additional risk management measures or operational conditions shall be implemented

to further reduce exposure to Cr(VI) to a level as low as is technically and practically feasible.

4. Until the technical improvements referred to in paragraph 2 are implemented and the exposure to Cr(VI) is reduced to a level as low as technically and practically feasible, the authorisation holder shall ensure that workers involved in the manual plating line and manual brushing use appropriate respiratory protective equipment, taking into account the duration of the tasks and the comfort of the worker during their use.

5. The authorisation holder shall ensure that workers:

   (a) are provided with adequate respiratory equipment, which is subjected to a fit test prior to its first use;

   (b) always perform a fit check of the seal of their respiratory protective equipment before starting a relevant task;

   (c) are adequately supported to undergo the fit tests referred to in point (a) and trained to undertake the fit checks referred to in point (b).

6. The authorisation holder shall carry out by 29 July 2025, and afterwards each time when new relevant information becomes available, a study to assess the feasibility of implementing the following measures:

   (a) the substitution of solid chromium trioxide flakes with liquid chromium trioxide solutions or installation of a closed/automated system to perform the dissolution of solid chromium trioxide and any subsequent (re-)filling of the baths with liquid solutions;

   (b) the installation of an automated system to perform the bath adjustment;

   (c) the installation of a closed or automatic system to perform bath sampling tasks, where exposure to Cr(VI) is expected;

   (d) the installation of a system that continuously controls the local exhaust ventilation and automatically triggers an alarm in case the local exhaust ventilation is not functioning properly and the installation of appropriate and effective measures to reduce the exposure to workers in case the local exhaust ventilation is not functioning properly..

   The authorisation holder shall act in accordance with the outcome of that study.

7. The authorisation holder shall ensure that workers wear appropriate respiratory protection equipment during bath sampling until the task is performed with an automated system or closed sampling system.

8. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The programme shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in exposure of workers to Cr(VI);

   (b) be based on relevant standard methodologies or protocols;

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise personal or static inhalation exposure sampling;

(e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, the operational conditions and risk management measures for each of those tasks, and of the total number of workers that are potentially exposed;

(f) be recorded so as to include contextual information about the tasks performed during exposure sampling.

9. The authorisation holder shall continue to conduct a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).

10. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 8 and 9 to review, at least annually, the appropriateness and effectiveness of risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, based on the outcome of this review, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to Cr(VI). Such measures shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

11. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 8 and 9, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and studies and any measure taken in accordance with paragraphs 2 to 7 and 10, and shall make that information available, including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 4

1. The review period shall expire on 7 February 2034.

2. The authorisation shall cease to be valid on 7 February 2034 with regard to an authorised use if the authorisation holder has not submitted the review report for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 7 September 2032.

Article 5

1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air and wastewater. The programme shall include measurements which shall:

(a) take place at least annually or more frequently if the production process is modified, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);

(b) be based on relevant standard methodologies or protocols;

(c) ensure a sufficiently low limit of quantification;

(d) be representative of the operational conditions and risk management measures used at the site where the authorised uses take place;

(e) be recorded so as to include contextual information associated with each set of measurements.

3. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraph 2 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the exposure of the general population via the environment. If needed, based on the outcome of this review, the authorisation holder shall introduce measures to further reduce to as low a level as technically and practically possible Cr(VI) emissions to the environment.

4. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any measure taken in accordance with paragraph 3. The authorisation holder shall make that information available, upon request, to the competent authority of the Member State where the authorised uses take place.

5. The authorisation holder shall document the steps taken to substitute chromium trioxide in accordance with the substitution plans, including information on the efforts to convince the authorisation holder's customers to accept alternative Cr(VI)-free solutions and justification in case its customers do not accept alternative Cr(VI)-free solutions. Any deviations from the initial substitution plans and information on contingency measures taken shall also be documented. The authorisation holder shall make such documentation available, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 6

If a review report is submitted, it shall include the information referred to in Article 2(8), Article 3(11), as well as Article 5(4) and (5).

Article 7

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised uses take place. The brief summary shall be drafted in an official language of that Member State.

Article 8

This Decision is addressed to:

Liebherr-Aerospace Lindenberg GmbH, Pfänderstrasse 50-52, 88161 Lindenberg, Germany.

Done at Brussels, 29.7.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION