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COMMISSION IMPLEMENTING DECISION

of 24.1.2025

partially granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Sarrel and Sarreliber - Transformação de Plásticos e Metais, S.A., for a use 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/EC¹, 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 9 November 2021, Sarrel and Sarreliber - Transformação de Plásticos e Metais, S.A., ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of chromium trioxide. The use for which authorisation was sought is for the etching of plastics materials, as a pre-treatment step of the electroplating process, for automotive applications mostly.
- (3) The European Chemicals Agency sent the opinions² on the application 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 23 February 2023, the Commission received the opinions.
- (4) In its opinion, 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 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.

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/10162/56c77d40-3b90-3a73-451f-764a06323e4b>

- (5) The chemicals safety report provided in the application includes only one exposure scenario. However, since the risk management measures and operational conditions differ at the two sites where the use of chromium trioxide described in the application takes place, for legal clarity, it is appropriate to reflect that differentiation by providing two exposure scenarios to be covered by this Decision. Therefore, the site of Sarrel should be referred to as exposure scenario 1 ('ES1') and the site of Sarreliber - Transformação de Plásticos e Metais, S.A., as exposure scenario 2 ('ES2').
- (6) In its opinion, 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. However, RAC expressed moderate concerns regarding the operational conditions during the manual handling of solid chromium trioxide while performing bath concentration adjustments, manual sampling as well as due to the absence of a continuous control system for the correct functioning of the local exhaust ventilation systems. Consequently, 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. Moreover, in order to address moderate shortcomings in exposure and emissions estimates and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions in place, RAC recommended monitoring arrangements for both the occupational exposure to Cr(VI) and the environmental release of it.
- (7) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that, as regards ES2, the estimated excess cancer risk values for the general population, exposed via the environment, 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 environmental emissions, recommended by RAC as monitoring arrangements, as a condition for authorisation for ES2.
- (8) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the use of chromium trioxide described in the application. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicants have demonstrated that the benefits of the continued use outweigh the risk to human health arising from that use.
- (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 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 opinion, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicants and in the Union at the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and the relevant information available, considers that there are technically and economically feasible alternatives which are commercially available in the Union, providing the overall functionality of the substance at least for one of the three plastics substrates covered by the use applied for, as also highlighted in one SEAC minority position on another application for authorisation for the same use³. The Commission, however, recognises that for the other two plastic substrates the identified alternatives imply a loss of performance in terms of, amongst others, adhesion, thermal and mechanical resistance. The Commission therefore agrees with SEAC's conclusion that there are no suitable alternatives for the applicants but concludes that suitable alternatives are available in the Union.
- (12) In its opinion, SEAC concluded that the substitution plan submitted by the applicants is credible and consistent with the analysis of alternatives and 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 use for which an authorisation is sought and the substitution plan submitted by the applicants, that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternative substances or technologies.
- (13) The applicants have clarified that the scope of the use applied for covers the etching of plastics materials, as a pre-treatment step of the electroplating process, for automotive applications only. Therefore, the Commission considers it appropriate to limit the authorised use accordingly.
- (14) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of chromium trioxide described in this Decision, 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.
- (15) 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 holders to generate and include additional information about exposure and emissions in the review report.
- (16) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 8 years. The Commission takes into account that recommendation, considering the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management

³ Application for authorisation submitted for uses of chromium trioxide submitted by Maier S. Coop. and others (Use ID: 0270-01/2).

measures are appropriate and effective in limiting the risk, SEAC's conclusions on the socio-economic benefits and costs of the continued use of the substance, as well as the time needed to replace chromium trioxide at industrial scale.

- (17) Nevertheless, the Commission recalls that the aim of the authorisation system is to ensure that substances of very high concern are progressively replaced by suitable alternative substances or technologies where they are available and technically and economically viable. Applicants should therefore make all efforts to achieve a complete phase-out of those substances by the end of a review period. The Commission also considers that there is increasingly available information on substitution of Cr(VI) substances for similar uses, including from similar applications for authorisation and relevant SEAC opinions, indicating that the applicants could be able to substitute more rapidly. In order to ensure that substitution of chromium trioxide is achieved as early as possible for the use authorised, and considering the potential risks posed by that use, the Commission considers that a shorter review period is appropriate.
- (18) 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 holders 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.
- (19) This Decision does not affect the obligation of the authorisation holders 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 holders 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 Council⁴ 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/EEC⁵, 92/85/EEC⁶, 94/33/EC⁷, 98/24/EC⁸ and Directive 2004/37/EC, or any

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>).

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

- (20) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC⁹ or Directive 2010/75/EU¹⁰ 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 Council¹¹ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹². 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.
- (21) 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 persons for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/25/3/0	Sarrel	Industrial use for the etching of plastics materials, as a pre-treatment step of the electroplating process, for automotive applications
REACH/25/3/1	Sarreliber - Transformação de Plásticos e	

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>).

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 not granted for the use of chromium trioxide in the etching of plastic materials for applications other than automotive applications.

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹³, and to the conditions set out in Articles 2 and 3.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 and 3.
2. By 24 January 2026, and afterwards each time that new relevant information becomes available, the authorisation holders shall carry out a study to assess the feasibility of implementing the following measures:
 - (a) the substitution of solid chromium trioxide flakes by liquid chromium trioxide 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 implementation of appropriate and effective measures to reduce the exposure of workers in case the local exhaust ventilation is not functioning properly.

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

3. The authorisation holders shall document and maintain the information on the outcome and conclusions of the feasibility study and on any measure taken in accordance with paragraph 2 and shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The authorisation bearing number REACH/25/3/1 is subject to the conditions set out in paragraphs 2 to 4.
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 a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);

¹³ <https://ec.europa.eu/docsroom/documents/53817>

- (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 use takes 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 via 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 a level as low as technically and practically possible Cr(VI) emissions to the environment.
4. The authorisation holder shall document and maintain the information gathered via the monitoring programmes 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 action taken in accordance with paragraph 3, and shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 4

The review period shall expire on 31 December 2028.

The authorisation shall cease to be valid on 31 December 2028 in relation to any authorisation holder who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2027.

Article 5

1. The monitoring arrangements set out in paragraphs 2 to 7 apply.
2. The authorisation holders 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.
3. The authorisation holders shall conduct a biomonitoring programme for all workers potentially exposed to Cr(VI).
 4. As regards the authorisation bearing number REACH/25/3/0, 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 a significant increase of chromium trioxide consumption takes place on site, 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 use takes place;
 - (e) be recorded so as to include contextual information associated with each set of measurements.
 5. The authorisation holders shall use the information gathered via the measurements referred to in paragraphs 2, 3 and, if applicable, paragraph 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holders shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers and, if applicable, their assessment of the exposure of the general population via the environment. If needed, based on the outcome of these reviews, the authorisation holders shall introduce measures to further reduce to a level as low as technically and practically possible workplace exposure to Cr(VI) and, if applicable, Cr(VI) emissions to the environment. Measures introduced to reduce occupational exposure shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.
 6. The authorisation holders shall document and maintain the information from the monitoring programmes referred to in paragraphs 2, 3 and, if applicable, paragraph 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measure taken in accordance with paragraph 5, 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.
 7. The authorisation holders shall document the steps taken to substitute chromium trioxide, including information on the efforts to convince the authorisation holders' customers to accept alternative Cr(VI)-free solutions and justification in case their customers do not accept alternative Cr(VI)-free solutions. Information on any contingency measures taken shall also be documented. The authorisation holders shall make such documentation available, upon request, to the competent authority of the Member States where the authorised use takes place.

Article 6

If a review report is submitted, it shall include the following:

- (a) information referred to in Article 2(3), Article 5(6) and (7), and, if applicable, Article 3(4);
- (b) a detailed justification as to why a complete phase-out of chromium trioxide is not expected to be achieved by the end of the review period;
- (c) figures detailing the reduction of the quantity of chromium trioxide used in the authorised use, as part of the substitution plan to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006.

Article 7

Upon request, the authorisation holders 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 use takes place. The brief summary shall be drafted in an official language of that Member State.

Article 8

This Decision is addressed to:

- (1) Sarrel, 38 rue Paul Chevalier, 72260 Marolles les Braults, Sarthe – Pays de la Loire, France;
- (2) Sarreliber - Transformação de Plásticos e Metais, S.A, Parque Empresarial de Mogueiras-Tabaço Arcos de Valdevez 4970-685, Arcos de Valdevez, Portugal.

Done at Brussels, 24.1.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

