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COMMISSION IMPLEMENTING DECISION

of 31.8.2017

granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Praxair Surface Technologies GmbH)

(ONLY THE GERMAN 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 therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 23 November 2015, Praxair Surface Technologies GmbH in its legal capacity as only representative of Praxair Surface Technologies, Inc. ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for two uses of chromium trioxide mixtures. The first use of the chromium trioxide mixture ('use 1') is for the industrial spraying or brush application of chromium trioxide mixtures for the coating of metallic articles subject to harsh environment, to ensure a high temperature corrosion and oxidation resistance, as well as anti-fouling properties or lubricity at high temperature, for automotive, aviation, power generation machinery, oil and gas and marine applications. The second use of the chromium trioxide mixture ('use 2') is for the industrial spraying of chromium trioxide mixtures for the coating of metallic articles subject to harsh environment to ensure either a low temperature-cured coating for corrosion protection, or a high temperature corrosion and oxidation resistance with reduction of surface roughness or a high temperature adhesive, for aviation, power generation machinery, oil and gas and marine applications.

(3) On 20 September 2016, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] on the application pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

[1] OJ L 396, 30.12.2006, p. 1.

[2] https://echa.europa.eu/documents/10162/fd2a2b0f-bd0b-4126-98c7-8f21b2da8ca8

(4) In its opinions, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of chromium trioxide in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore chromium trioxide is a non-threshold substance. In accordance with Article 60(3)(a) of Regulation (EC) No 1907/2006, Article 60(2) of that Regulation does not apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

(5) In its opinions, RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and to the general population that could be potentially exposed via the environment.

(6) In its opinions, RAC identified some uncertainties related to the data on workers' exposure and on indirect exposure of man via the environment. While considering that the exposure of workers and of man via the environment as calculated by the applicant is acceptable for risk characterisation and impact assessment because of the worst case approach used, RAC recommended monitoring arrangements to strengthen the level of certainty of the actual exposure assessment.

(7) In its opinions, SEAC concluded that the overall socio-economic benefits arising from the two uses of chromium trioxide applied for outweigh the risks to human health or the environment arising from those uses and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant. The Commission, having evaluated the SEAC assessments, concurs with these conclusions.

(8) Based on the RAC and the SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of chromium trioxide applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report[3], as well as the monitoring arrangments set out in this Decision, are fully applied.

(9) In its opinion, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at seven years for use 1 and twelve years for use 2. The recommended review period for use 1 takes into account the low costs associated with the risks that arise from the continued use of the substance, the lack of suitable alternatives that will be available by the sunset date, the applicant's research and development activities to develop alternatives with a comparable performance, the applicant's request for a review period of seven years to implement the alternatives within a credible and justified timeframe, the likelihood that substitution would not be possible within shorter timelines, as well as the fact that the benefits of continued use outweigh the risks by a significant margin. The recommended review period for use 2 takes into account the negligible costs associated with the risks that arise from the continued use of the substance, the lack of suitable alternatives that will be available by the sunset date, the applicant's credible and justified plan for research and development activities to develop and implement alternatives with a comparable performance, the likelihood that substitution would not be possible within shorter timelines, as well as the fact that the benefits of continued use outweigh the risks by a significant margin.

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[3] https://echa.europa.eu/documents/10162/e2e0d8fe-03ea-438b-8cc0-a9f0acab8d81
http://ec.europa.eu/DocsRoom/documents/20582

(10) Therefore, the Commission considers appropriate that, as regards the two uses of chromium trioxide applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at seven years for use 1 and twelve years for use 2 from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(11) Concerning use 1, the application referred to the use of chromium trioxide for its 'anti-fouling properties'. Such description of use may create confusion with the use of chromium trioxide as a biocidal product as defined in Article 3(1)(a) of Regulation (EU) No 528/2012 of the European Parliament and of the Council[4]. Under that Regulation chromium trioxide cannot be placed on the market nor used as a biocidal product and this Decision cannot authorise such use, in accordance with Article 56(4)(b) of Regulation (EC) No 1907/2006. Therefore, to avoid confusion, the term 'anti-fouling properties' should be replaced by 'deposit-resistant properties of the surface' in the description of use 1 as authorised by this Decision, as chromium trioxide is in fact used for that latter function.

(12) The language used for the description of the risk management measures and operational conditions included in the application for authorisation may be different from the official language(s) of the Member State(s) where the use(s) take(s) place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State(s) concerned.

(13) This Decision does not affect the obligation of the authorisation holder to ensure that the use does not adversely affect human health or the environment pursuant to Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect either the obligation of the authorisation holder to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible pursuant to Article 60(10) of Regulation (EC) No 1907/2006 or the obligation of the employer to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible in accordance with Article 4(1) of Directive 2004/37/EC of the European Parliament and of the Council[5], or to prevent and reduce exposure in accordance with Article 5 of that Directive. Furthermore, this Decision is without prejudice to the application of the EU Directives in the area of health and safety at work, in particular Council Directive 89/391/EEC[6], Council Directive 98/24[7],

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4 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

5 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 L 158, 30.4.2004, p. 50).

6 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, 29.06.1989, p. 1).

7 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, 05.05.1998, p. 11).

Directive 2004/37 of the European Parliament and of the Council[8], Council Directive 92/85/EEC[9] and Council Directive 94/33/EC[10].

(14) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directive 2010/75/EU of the European Parliament and of the Council[11] and Directive 2008/50/EC of the European Parliament and of the Council[12], as well as with emission limit values set to achieve compliance with the environmental quality standards established both in Directive 2008/105/EC of the European Parliament and of the Council[13] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[14]. Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.

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

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of chromium trioxide (EC No 215-607-8 and CAS No 1333-82-0) provided that the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation, as well as the monitoring arrangments set out in this Decision are fully applied:

Authorisation number	Authorised use
REACH/17/X/0	Industrial spraying or brush application of chromium trioxide mixtures for the coating of metallic articles subject to harsh environment, to ensure a high temperature corrosion and oxidation resistance, as well as deposit-resistant properties of the surface or lubricity at high temperature, for automotive, aviation,

8 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 L 158, 30.04.2004).

9 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).

10 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.08.1994, p. 12).

11 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).

12 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).

13 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).

14 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).

	power generation machinery, oil and gas and marine applications
REACH/17/X/1	Industrial spraying of chromium trioxide mixtures for the coating of metallic articles subject to harsh environment to ensure either a low temperature-cured coating for corrosion protection, or a high temperature corrosion and oxidation resistance with reduction of surface roughness or a high temperature adhesive, for aviation, power generation machinery, oil and gas and marine applications

Article 2

As regards the authorised uses of chromium trioxide, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2024 for use 1 with authorisation number REACH/17/X/0 and on 21 September 2029 for use 2 with authorisation number REACH/17/X/1.

Article 3

The following monitoring arrangements shall apply:

(a) the authorisation holder shall submit, upon request, to the competent authority of the Member State where the authorised use takes place a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report in an official language of that Member State;

(b) the authorisation holder shall conduct regular occupational exposure measurements relating to all manual spraying tasks for the uses described in Article 1. This monitoring shall:

  (i) take place at least annually;

  (ii) be performed at all sites where manual spraying is performed;

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

  (iv) include, in addition to air monitoring, also biomonitoring;

(c) the authorisation holder shall regularly measure the emissions of chromium VI into the air relating to the uses referred to in Article 1 at all sites. Measurement campaigns shall be undertaken according to standard sampling and analytical methods and have a sufficiently low detection limit,where appropriate;

(d) the authorisation holder shall use the information gathered in the measurements referred to in points (b) and (c) to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate. In particular, the manual spraying shall be replaced by automated spraying and where this is not possible, the reasons for not doing so shall be documented;

(e) the authorisation holder shall develop exposure scenarios for maintenance tasks, including tasks related to change of filters;

(f) the results of the measurements referred to in points (b) and (c), as well as the outcome and conclusions of the review and any actions taken in accordance with point (d) together with the exposure scenarios described in point (e) shall be documented and included in the review report referred to in Article 61(1) of

Regulation (EC) No 1907/2006 and, upon request, shall be submitted to the competent authority of the Member State where the authorised use takes place.

Article 4

This Decision is addressed to Praxair Surface Technologies GmbH, in its legal capacity as only representative of Praxair Surface Technologies, Inc., Am Muehlback 13, 87487 Wiggensbach, Germany.

Done at Brussels, 31.8.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION