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COMMISSION IMPLEMENTING DECISION

of 10.10.2017

granting an authorisation for a use of chromium trioxide in Cr(VI)-based functional plating under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Oy Kromatek Ab)

(ONLY THE ENGLISH, FINNISH AND SWEDISH TEXTS ARE 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 is therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.
- (2) On 1 October 2015, an application for authorisation was submitted by Oy Kromatek Ab, Cr-Te Plating Oy, Kova-Kromi Oy, Pirkan Kovakromaus Oy, Saizeri Plating Oy, Turun Kovakromi Oy and Veljekset Wallenius Oy ('the applicants') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of chromium trioxide in Cr(VI)-based functional plating.
- (3) On 29 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 Agency² on the application pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) In its opinion, 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 opinion, RAC concluded that the risk management measures and operational conditions as described in the application are not appropriate and effective in limiting

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/4908b8e1-3be2-4a8e-9bd4-c83539b8379f>

the risk to workers and to the general population that could be potentially exposed via the environment.

- (6) In its opinion, due to uncertainties related to worker exposure assessment (i.e. there are considerable differences in exposure levels and in the systematic implementation of appropriate risk management measures between the sites covered by the application, certain tasks with high potential for exposure have not been properly covered by monitoring and assessed solely based on modelling or the monitoring design which has not allowed high exposure to be clearly associated with specific tasks), RAC recommended additional conditions and monitoring arrangements.
- (7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of chromium trioxide applied for outweigh the risks to human health or the environment arising from that use and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicants.
- (8) Based on the RAC and SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is therefore appropriate to authorise the use 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 report³, as well as additional conditions and monitoring arrangements 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. The recommended review period takes into account on one hand the lack of suitable alternatives by the sunset date and the likelihood that suitable alternatives would not become available to the applicants within shorter timelines, the applicants' position in the supply chain as small service providers, their dependence on the industry sector in view of substitution and product performance, their difficulties in accessing capital to invest in new technologies, and on the other hand the reservations about the long term technical infeasibility of the Cr(III)-based functional plating alternative, the vagueness regarding their future substitution efforts, the uncertainties concerning the extent to which recertification is necessary for all of the applicants' customers and overall the fact that the request for a longer review period than seven years is not sufficiently justified.
- (10) Therefore, as regards the use of chromium trioxide applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at seven years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (11) 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 authorisation holders 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.
- (12) 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

³ <http://ec.europa.eu/DocsRoom/documents/20639>

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 Council⁴, 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/EEC⁵, Council Directive 98/24⁶, Directive 2004/37 of the European Parliament and of the Council⁷, Council Directive 92/85/EEC⁸ and Council Directive 94/33/EC⁹.

- (13) 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 Council¹⁰ and Directive 2008/50/EC of the European Parliament and of the Council¹¹, 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 Council¹² and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council¹³. 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.
- (14) 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,

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 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).

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, 29.06.1989, p. 1).

⁶ 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).

⁷ 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).

⁸ 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).

⁹ 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).

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).

¹¹ 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).

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).

¹³ 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).

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 use 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 conditions and monitoring arrangements set out in Articles 2 and 4 of this Decision, are fully applied:

Authorisation number	Authorisation holder	Authorised use
REACH/17/22/0	Oy Kromatek AB	Use of chromium trioxide in Cr(VI)-based functional plating
REACH/17/22/1	Cr-Te Plating Oy	
REACH/17/22/2	Kova-Kromi Oy	
REACH/17/22/3	Pirkan Kovakromaus Oy	
REACH/17/22/4	Saizeri Plating Oy	
REACH/17/22/5	Turun Kovakromi Oy	
REACH/17/22/6	Veljekset Wallenius Oy	

Article 2

The authorisation referred to in Article 1 shall be subject to the following conditions:

- (a) the authorisation holders shall develop without delay and at the latest by 10 April 2018 in cooperation with (an)expert(s), a strategy for reducing exposure to Cr(VI) and shall implement this strategy at all sites by 10 April 2019. This strategy shall comply with the following minimum requirements:
 - (i) ensuring proper design and effectiveness of the following engineering risk management measures and operational conditions for each plating bath:
 - extent of enclosure/covering;
 - mist and fume suppression by chemical or other applicable means;
 - local exhaust ventilation (LEV);
 - (ii) complying with the following organisational measures:
 - update of all protocols/ procedures (this should also include the tasks of maintenance and rinsing of plated items);
 - organisation of work practices to control access to and shorten the time of work in work areas with high Cr(VI) concentrations in air;
- (b) the authorisation holders shall implement regularly, and at least annually, measurements of Cr(VI) concentration in workplace air relating to the use referred to in Article 1 at all sites, based on relevant standard methodologies or protocols as follows:

- (i) all tasks where exposure to Cr(VI) is possible shall be covered;
 - (ii) those measurements shall be representative for all the workers that are potentially exposed;
 - (iii) reports providing results of measurements, but also describing the tasks performed by the respective workers and the risk management measures used during air sampling, shall be provided;
 - (iv) in case static samplers are used, their location in relation to sources of Cr(VI) emission at each particular site shall be described and shown on a site map;
- (c) the information gathered in the measurements required by point (b) shall be used to regularly review the effectiveness of the risk management measures and operational conditions and to take action as appropriate; it shall be documented, maintained and be available to national enforcement authorities.

Article 3

As regards the authorised use 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.

Article 4

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 strategy as described in Article 2(a), the results of the measurements as described in Article 2(b), as well as the outcome and conclusions of the review and any actions taken as described in Article 2(c), shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place. In addition, the following information shall be included in the review report:
 - (i) information about the tasks performed by workers exposed to Cr(VI) at the time the samples (urine) are taken and the risk management measures used. The sampling shall cover those tasks related to the cleaning of the plating baths (samples taken before and after the task);
 - (ii) records and a summary of the content of regular specific training for all workers regarding safe work practices related to potential exposure to Cr(VI) during plating activities;
 - (iii) results of measurements of environmental releases to air and, where applicable, to water.

Article 5

This Decision is addressed to:

1. Oy Kromatek Ab, Heikkiläntie 4, 29250 Nakkila, Finland;
2. Cr-Te Plating Oy, Leijukuja 17, 78210 Varkaus, Finland;

3. Kova-Kromi Oy, Hankikuja 2, 01390 Vantaa, Finland;
4. Pirkan Kovakromaus Oy, Lempäälänkuja 5, 33840 Tampere, Finland;
5. Saizeri Plating Oy, Kiilatie 3, 40320 Jyväskylä, Finland;
6. Turun Kovakromi Oy, Kuparitie 5, 28330 Pori, Finland;
7. Veljekset Wallenius Oy, Rantakaari 69, 37200 Siuro, Finland.

Done at Brussels, 10.10.2017

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission