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**COMMISSION IMPLEMENTING DECISION**

**of 13.6.2017**

**granting an authorisation for a use of potassium dichromate under Regulation (EC) No  
1907/2006 of the European Parliament and of the Council (Sofradir)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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**granting an authorisation for a use of potassium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Sofradir)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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<sup>1</sup>, and in particular Article 64(8) thereof,

Whereas:

- (1) Potassium dichromate 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 20 November 2015, an application for authorisation was submitted by Sofradir ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the industrial use of potassium dichromate-based mixtures during the steps of initial and final etching of Cadmium Zinc Telluride (CZT) layers during the production of opto-electronic components gathering a readout and an infrared detecting circuit with the Mercury Cadmium Telluride (MCT) technology ('use 1'), and for the industrial use of potassium dichromate-based mixtures during the etching of both Indium Antimonide (InSb) substrate sides during the production of opto-electronic components gathering a readout and an infrared detecting circuit with the InSb technology ('use 2').
- (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<sup>2</sup> on the application pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) In its opinion, the RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic and mutagenic properties of potassium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore that potassium dichromate is a non-threshold substance. In

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> <https://echa.europa.eu/documents/10162/c916c7c8-060a-4070-bf0f-362061ab5cfa>  
<https://echa.europa.eu/documents/10162/5a8e3c32-3d3e-4e30-b998-1a905b7077b9>

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, for both uses, the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population that could potentially be exposed via the environment.
- (6) In its opinions on both uses, due to uncertainties related to the lack of measurements for emissions to the air and to low number of measurements for workers' inhalation exposure, RAC recommended additional monitoring of emissions to the air, as well as additional occupational exposure measurements.
- (7) In its opinions, SEAC concluded that the overall socio-economic benefits arising from the uses of potassium dichromate 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 feasibility for the applicant.
- (8) Based on the RAC and SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the uses of potassium dichromate applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report<sup>3</sup>, as well as the additional conditions and monitoring arrangements set out in this Decision, are fully applied.
- (9) In its opinions, 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 at four years for use 2. The recommended review periods take into account the low costs associated with the risks that arise from the continued use of the substance, the lack of suitable alternatives by the sunset date, the applicant's request and credible justification for a review period of seven years for use 1 and of four years for use 2 in order to perform the development, implementation and qualification of a technically and economically feasible alternative, as well as the fact that the benefits of continued use outweigh the risks by a significant margin.
- (10) Therefore, as regards the uses of potassium dichromate applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at seven years for use 1 and at four years for use 2 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 uses take place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the authorisation holder 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

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<sup>3</sup> <http://ec.europa.eu/DocsRoom/documents/19104>  
<http://ec.europa.eu/DocsRoom/documents/19105>

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<sup>4</sup>, 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<sup>5</sup>, Council Directive 98/24<sup>6</sup>, Directive 2004/37 of the European Parliament and of the Council<sup>7</sup>, Council Directive 92/85/EEC<sup>8</sup> and Council Directive 94/33/EC<sup>9</sup>.

- (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 Council<sup>10</sup> and Directive 2008/50/EC of the European Parliament and of the Council<sup>11</sup>, 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<sup>12</sup> and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council<sup>13</sup>. 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,

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<sup>4</sup> 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).

<sup>5</sup> 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).

<sup>6</sup> 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).

<sup>7</sup> 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).

<sup>8</sup> 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).

<sup>9</sup> 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).

<sup>10</sup> 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).

<sup>11</sup> 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).

<sup>12</sup> 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).

<sup>13</sup> 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 uses of potassium dichromate (EC No: 231-906-6 and CAS No: 7778-50-9), 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	Authorised use
REACH/17/14/0	Industrial use of potassium dichromate-based mixtures during the steps of initial and final etching of CZT layers during the production of opto-electronic components gathering a readout and an infrared detecting circuit with the MCT technology
REACH/17/14/1	Industrial use of potassium dichromate-based mixtures during the etching of both InSb substrate sides during the production of opto-electronic components gathering a readout and an infrared detecting circuit with the InSb technology

*Article 2*

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

- (a) the authorisation holder shall measure at least once a year emissions of chromium (VI) to the air related to the uses of potassium dichromate referred to in Article 1. The measurements shall be undertaken according to standard sampling and analytical methods;
- (b) the information gathered in the measurements required by point (a) shall be used to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate; that information, as well as the outcome and conclusion of the review of the risk management measures and operational conditions shall be documented and, upon request, be submitted to the competent authority of the Member State(s) where the authorised uses take place;
- (c) the results of the measurements required by point (a), as well as the outcome and conclusions of the review and any actions taken, as described in point (b), shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

*Article 3*

As regards the authorised uses of potassium dichromate, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2024 for the use with authorisation number REACH/17/14/0 and on 21 September 2021 for the use with authorisation number REACH/17/14/1.

#### *Article 4*

The following monitoring arrangements shall apply:

- (a) upon request of the competent authority of a Member State where an authorised use takes place, the authorisation holder shall submit to that authority 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 related to the uses described in Article 1. This monitoring shall:
  - (i) take place at least annually;
  - (ii) be based on relevant standard methodologies or protocols;
  - (iii) be representative of the range of tasks with possible exposure to chromium (VI) and of the total number of workers that are potentially exposed;
- (c) the information gathered in the monitoring 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; that information, as well as the outcome and conclusion of the review of the risk management measures and operational conditions shall be documented and, upon request, be submitted to the competent authority of the Member State(s) where the authorised uses take place;
- (d) the results of the monitoring required by point (b), as well as the outcome and conclusions of the review and any actions taken, as described in point (c), shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

#### *Article 5*

This Decision is addressed to Sofradir, Avenue de la Vauve, 91120 Palaiseau, France.

Done at Brussels, 13.6.2017

*For the Commission*  
*Elżbieta BIENKOWSKA*  
*Member of the Commission*

