



Brussels, 10.7.2019  
C(2019) 5022 final

**COMMISSION IMPLEMENTING DECISION**

**of 10.7.2019**

**granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (ZF Friedrichshafen AG)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

# COMMISSION IMPLEMENTING DECISION

of 10.7.2019

**granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (ZF Friedrichshafen AG)**

(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) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and is therefore subject to the authorisation requirement laid down in Article 56(1)(a) of that Regulation.
- (2) On 17 May 2017, ZF Friedrichshafen AG ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of chromium trioxide for functional chrome plating of piston rods for automotive and rail applications.
- (3) On 13 March 2018, 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, 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 that therefore chromium trioxide is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. Pursuant to Article 60(3)(a), Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance and therefore an authorisation may only be granted in accordance with 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 appropriate and effective in limiting the risk to workers and to members of the general population who could potentially be

---

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

<sup>2</sup> <https://echa.europa.eu/documents/10162/8e5ecc0a-e5ef-4f16-9be9-5ecf587d57f4>

exposed via the environment. However, RAC considered that the exposure assessment should be supplemented with additional monitoring data to increase its reliability and recommended monitoring arrangements in that regard. The Commission, having evaluated RAC's assessment, concurs with its conclusions and recommendation.

- (6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of chromium trioxide covered by the application outweigh the risk to human health arising from that use and that there are no suitable alternative substances or technologies at the sunset date. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.
- (7) 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 covered by the application, provided that the risk management measures and operational conditions described in the chemical safety report, referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006, are fully applied.
- (8) 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 twelve years. The Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the conclusion that the risk management measures and operational conditions are appropriate and effective in limiting the risk, the conclusion that the socio-economic benefits of continued use outweigh the risk to human health by a significant margin, the long investment cycle of the applicant, the time for the development and testing of the most promising alternative, the conclusion that the situation is unlikely to change in the next decade and the fact that no major uncertainties were identified in the analysis of alternatives or in the socio-economic assessment.
- (9) Therefore, it is appropriate, as regards the use of chromium trioxide applied for, to set the review period at 12 years. Given that the applicant submitted its application for authorisation after the latest application date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 and that the sunset date set out in Annex XIV to that Regulation has already passed at the time of the adoption of this Decision, it is appropriate to set the starting point for the review period as from the adoption of this Decision.
- (10) 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 of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require 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 concerned.
- (11) 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 having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect 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 and 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>3</sup>, or to prevent and reduce exposure in accordance with Article 5 of that Directive. 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<sup>4</sup>, 92/85/EEC<sup>5</sup>, 94/33/EC<sup>6</sup>, and 98/24/EC<sup>7</sup> and Directive 2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

- (12) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC<sup>8</sup> or Directive 2010/75/EU<sup>9</sup> of the European Parliament and of the Council, nor 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<sup>10</sup> or established in Directive 2008/105/EC of the European Parliament and of the Council<sup>11</sup>. Compliance with the provisions of this Decision does not necessarily imply compliance with other emission limit values or environmental quality standards under Union legislation, as those may include separate or more onerous requirements.
- (13) 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 use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorised use
REACH/19/25/0	Use for functional chrome plating of piston rods for automotive and rail

<sup>3</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>4</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, 29.6.1989, p. 1).

<sup>5</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>6</sup> 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).

<sup>7</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, 5.5.1998, p. 11).

<sup>8</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>9</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>10</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).

<sup>11</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).

## applications

The authorisation is granted subject to the full application of the risk management measures and operational conditions described in the chemical safety report<sup>12</sup>.

### *Article 2*

1. The review period shall expire on 10 July 2031.
2. The authorisation shall cease to be valid on 10 July 2031 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 10 January 2030.

### *Article 3*

The following monitoring arrangements shall apply:

- (a) the authorisation holder shall conduct regular occupational exposure measurements related to the use referred to in Article 1. Those measurements shall:
  - (i) take place at least annually;
  - (ii) be performed at and comparable for all sites;
  - (iii) be based on relevant standard methodologies or protocols and ensure sufficiently low detection limit;
  - (iv) comprise both static and personal inhalation exposure sampling, including biomonitoring;
  - (v) be representative of the range of tasks of workers and process steps with possible exposure to chromium (VI), including rare maintenance tasks included in the Working Contributing Scenario 7 "Rare Maintenance", in the chemical safety report referred to in Article 1, and of all the workers that are potentially exposed;
  - (vi) include contextual information about the tasks with possible exposure to chromium (VI).
- (b) The authorisation holder shall use the information gathered in the course of the measurements referred to in point (a) to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions in place at each site and to take action, if appropriate, to further reduce exposure of workers.
- (c) The authorisation holder shall document the results of the measurements referred to in point (a), as well as the outcome and conclusions of the review and any action taken in accordance with point (b) and submit that information, upon request, to the competent authority of the Member State where the authorised use takes place. The authorisation holder shall use that information to review and validate the exposure estimates in the chemical safety report and shall include it in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

---

<sup>12</sup> For use 1: <https://ec.europa.eu/docsroom/documents/25608>  
For use 2: <https://ec.europa.eu/docsroom/documents/25609>

*Article 4*

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 use takes place in an official language of that Member State.

*Article 5*

This Decision is addressed to ZF Friedrichshafen AG, Bogestrasse 50, 53783 Eitorf, Germany.

Done at Brussels, 10.7.2019

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

