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COMMISSION IMPLEMENTING DECISION

of 22.10.2019

**partially granting an authorisation for certain uses of chromium trioxide under
Regulation (EC) No 1907/2006 of the European Parliament and of the Council (ZF
Luftfahrttechnik GmbH)**

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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

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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 laid down in Article 56(1)(a) of that Regulation.
- (2) On 21 March 2016, ZF Luftfahrttechnik GmbH ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of chromium trioxide in functional chrome plating ('use 1') and in surface treatment for applications in the aeronautics and aerospace industries (unrelated to functional chrome plating or functional chrome plating with decorative character) ('use 2').
- (3) On 11 September 2017, 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 sent pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (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 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

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/099eca8e-5d54-6297-5860-8022047fa177>
<https://echa.europa.eu/documents/10162/c39fb90c-2eb2-0650-9745-23b5dc9ea0ea>

therefore an authorisation may only be granted in accordance with Article 60(4) of that Regulation.

- (5) In its opinions on uses 1 and 2, 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 exposed via the environment. However, as it is clear that the operational conditions and risk management measures for workers can be improved and due to uncertainties in the assessment of the exposure of members of the general public via environment, RAC recommended additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with its conclusion.
- (6) An alternative should be able to provide the level of technical performance functionally necessary for the use applied for to be considered technically feasible. Some potential alternatives may provide this functionality but at some loss to performance or in a manner that involves technical compromises. The Commission considers that, given the economic and other incentives towards substitution that already arise from inclusion in the authorisation system, and in the light of the objective of progressive substitution, as a starting point, the Commission should not consider a potential alternative technically viable where such losses to performance or technical compromises are not minor. Nevertheless, the Commission considers it must be possible to depart from this approach where justified by particular circumstances, including the specific function of the substance for the use applied for, the public interests at stake, or a low net balance of the socio-economic benefits and the risk to human health or the environment. The Commission also considers that no particular factors justify less strict technical feasibility requirements in this case. Where the Commission is able to conclude on lack of technically feasible alternatives to the substance, it is unnecessary to consider economic feasibility of substitution.
- (7) However, SEAC pointed out a discrepancy between the broad title of the two uses covered by the application and the more narrow description thereof in the socio-economic analysis provided by the applicant. SEAC also pointed out the uncertainties arising from the differences between the generic approach to the analysis of alternatives and the more narrow scope of the uses described in the socio-economic analysis. On that basis, SEAC recommended the authorisation to cover use of chromium trioxide in the production of transmissions for helicopters and maintenance of helicopters as described in the socio-economic analysis included in the application for authorisation. The Commission concurs with SEAC's recommendation and considers necessary to limit the scope of the two uses to the production of transmissions for helicopters and maintenance of helicopters. The Commission considers that the applicant discharged its burden of proof in demonstrating the absence of suitable alternatives only with regard to such limited scope of the use.
- (8) In its opinions, SEAC concluded that the overall socio-economic benefits from uses 1 and 2 outweigh the risk to human health arising from those uses and that there are no suitable alternative substances or technologies. The Commission, having evaluated SEAC's assessment, concurs with its conclusion and considers that as regards both uses the applicant has demonstrated that no potential alternatives provide the level of technical performance functionally necessary for the uses applied for.
- (9) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of chromium trioxide, as limited in this Decision, provided that the risk management measures and

operational conditions described in the application and in the chemical safety report referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006, as well as the conditions set out in this Decision, are fully applied. The authorisation should not be granted for the two uses in applications other than the production of transmissions for helicopters and maintenance of helicopters.

- (10) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC, and based its conclusions on the existence of a sufficient weight of evidence allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessments on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional exposure and emission information.
- (11) 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 uses 1 and 2. The Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the conclusions that the risk management measures and operational conditions are appropriate and effective in limiting the risk, that the socio-economic benefits of the continued uses clearly outweigh the risk, the long lifetime of the helicopters and the need to ensure the treatment of the legacy spare parts over long timeframes, the time needed for extensive testing, certification according to the airworthiness requirements and industrialisation of a suitable alternative, should one become available, as well as the uncertainty as to whether more time is needed to substitute some of the processes falling within the scope of the uses.
- (12) It is therefore appropriate to set a review period of seven years from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (13) 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 compliance with 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.
- (14) 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 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 Council³, 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

³ 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).

at work, in particular Council Directives 89/391/EEC⁴, 92/85/EEC⁵, 94/33/EC⁶ and 98/24/EC⁷ and Directive 2004/37/EC as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

- (15) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC⁸ or Directive 2010/75/EU⁹ 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 Council¹⁰ or established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. Compliance with the provisions of this Decision does not necessarily imply compliance with other emission limit values or environmental quality standards under Union law, as those may include further or more onerous requirements.
- (16) 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; CAS No 1333-82-0):

Authorisation number	Authorised use
REACH/19/27/0	Use as surface hardener (functional chrome plating) in the production of transmissions for helicopters and maintenance of helicopters
REACH/19/27/1	Surface treatment (as a corrosion inhibitor, unrelated to functional chrome plating) in the production of transmissions for helicopters and

⁴ 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).

⁵ 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).

⁶ 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).

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, 5.5.1998, p. 11).

⁸ 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).

⁹ 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).

¹⁰ 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).

¹¹ 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).

maintenance of helicopters

An authorisation is not granted for the use of chromium trioxide as surface hardener and in surface treatment other than in the production of transmissions for helicopters and maintenance of helicopters.

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹², as well as the conditions laid down in Article 2.

Article 2

The authorisation holder shall install a cover on the chromate bath 'tank 51' in order to reduce the workers' exposure to chromium (VI) and shall review the risk management measures for the chromate baths to ensure adequate protection of workers.

Article 3

1. The review period shall expire on 21 September 2024.
2. The authorisation shall cease to be valid on 21 September 2024 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 21 March 2023.

Article 4

1. The monitoring arrangements referred to in paragraphs 2 to 5 shall apply.
2. The authorisation holder shall continue to perform occupational exposure monitoring programmes of chromium (VI) related to the uses referred to in Article 1. Those workplace air monitoring programmes shall:
 - (a) be based on relevant standard methodologies and protocols;
 - (b) ensure a sufficiently low detection limit;
 - (c) be based on personal inhalation exposure sampling where possible;
 - (d) be representative of the range of tasks with possible exposure to chromium (VI) including, regarding the use bearing authorisation number REACH/19/27/0, the tasks described in the workers contributing scenarios 2, 3, 12 and 14 of the chemical safety report referred to in Article 1, and, regarding the use bearing authorisation number REACH/19/27/1, the tasks described in the workers contributing scenarios 2, 3, 4, 15, 17, 18, 19 and 21 of that chemical safety report. The measurements shall also be representative of all the workers that are potentially exposed.
3. At the latest by 22 October 2020 the authorisation holder shall ensure the effectiveness of the local exhaust ventilation by implementing appropriate preventive maintenance programmes.
4. The authorisation holder shall use the information gathered in the measurements referred to in paragraph 2 to review regularly the appropriateness and effectiveness

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

For use 2: <https://ec.europa.eu/docsroom/documents/25609>

of the risk management measures and operational conditions and to take action, as appropriate, to further reduce exposure of workers to chromium (VI).

5. The authorisation holder shall document the results of the measurements and the contextual information referred to in paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with paragraph 4, and submit them, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

If the authorisation holder submits a review report, it shall include the following:

- (a) the information referred to in Article 4(2) and (5);
- (b) a refined assessment of indirect exposure of and risk to the members of the general public via the environment that takes into account all reasonably foreseeable routes of exposure of humans, including the oral route, and the results of the measurements of emissions of chromium (VI) to wastewater.

Article 6

Upon request, the authorisation holder shall submit a succinct 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 7

This Decision is addressed to ZF Luftfahrttechnik GmbH, Flughafenstrasse, 34379, Calden, Germany.

Done at Brussels, 22.10.2019

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission