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COMMISSION IMPLEMENTING DECISION

of 8.4.2020

partially granting an authorisation for a use of dichromium tris(chromate) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Wesco Aircraft EMEA Limited)

(Only the English 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, in conjunction with Article 131 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community,

Whereas:

(1) Dichromium tris(chromate) 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 19 May 2017, Wesco Aircraft EMEA Limited, submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of dichromium tris(chromate) for chemical conversion coating applications by aerospace and defence sector.

(3) On 24 September 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[2] ('the Agency') on the application sent pursuant to the third 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 dichromium tris(chromate) in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore dichromium tris(chromate) is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. As a result, paragraph 2 of Article 60 of Regulation (EC) 1907/2006 does not apply to that substance, and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

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

[2] https://echa.europa.eu/documents/10162/45647a66-b5d3-ff9a-3a39-8f528af56a96

(5) RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk to workers and to the members of the general population who could be potentially be exposed via the environment. RAC concluded that there are significant uncertainties regarding worker exposure due to the fact that only qualitative and modelled exposure estimates were presented. RAC further noted that those uncertainties especially concern the machining operations on metallic surfaces since these activities were not covered in the design of the modelling tool used. RAC also pointed to concerns regarding the representativeness of the exposure scenarios for the whole supply chain covered by the application. These concerns relate to the lack of information on the characteristics of the sites that served for the development of the exposure scenarios. However, RAC acknowledged that releases to the air of chromium (VI) are likely to be low due to the low volatility of dichromium tris(chromate) and modern abatement technology with high efficiency.

(6) RAC further concluded that uncertainties also exist in the assessment of the indirect exposure of the members of the general population to the substance, via the environment, at the local level, as regards both exposure through inhalation and oral exposure. Furthermore, RAC did not fully support the applicants' statement that wastewater releases are negligible.

(7) RAC considered the risk assessment documented in the chemical safety report submitted by the applicant to be sufficient for assessing whether the socio-economic benefits outweigh the risk to human health pursuant to Article 60(4) of Regulation (EC) No 1907/2006. However, due to uncertainties related to the assessment of risks to workers and to the general population via the environment, RAC recommended additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with its conclusions and recommendations.

(8) An authorisation may be granted under Article 60(4) of Regulation (EC) No 1907/2006 if there are no suitable alternative substances or technologies. In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use applied for. 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 interest at stake, or a low net difference between 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.

(9) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of dichromium tris(chromate) covered by the application outweigh the risk to human health arising from that use. The Commission, having evaluated SEAC's assessment, concurs with that conclusion. In its opinion, SEAC concluded that there are no suitable alternative substances or technologies. Nevertheless, considering the

broadness of the definition of the scope of the use applied for, the Commission considers it necessary to limit the description of the use by aligning it with the conclusions of the analysis of alternatives as presented in the application and as assessed by SEAC The Commission considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives only with regard to such limited scope of use. Consequently, the description of the authorised use should be limited to refer only to uses where any of the following key functionalities or properties is necessary for the intended use: corrosion resistance, active corrosion inhibition, adhesion promotion, chemical resistance, layer thickness, electrical properties.

(10) The Commission considers that the applicant has demonstrated that no potential alternatives provide the level of technical performance functionally necessary for the use applied for as limited in this Decision.

(11) 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 dichromium tris(chromate) as limited in this Decision, 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, as well as the conditions set out in this Decision are fully applied. An authorisation should not be granted for the part of use where the specified key functionalities or properties are not necessary for the intended use.

(12) 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.

(13) Furthermore, in order to facilitate the enforcement of this Decision, the Commission considers necessary to require the authorisation holder's downstream users to include in the notification sent to the Agency pursuant to Article 66(1) of Regulation (EC) No 1907/2006 an explanation of the key functionalities or properties which are necessary for their use, including a justification why such key functionalities are necessary for that use (e.g. parts covered by safety certification and/or standards).

(14) In its opinion, SEAC recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 be set at seven years. The Commission concurs with that recommendation, taking into account the relevant elements from the assessments of RAC and SEAC and, in particular, RAC's assessment of the risk of the continued use of the substance and the conclusion that the risk management measures and operational conditions are not appropriate and effective, the recommended additional conditions and monitoring arrangements, together with the conclusion that the socio-economic benefits of continued use substantially outweigh the monetised risk to human health, the long investment cycle in the aerospace and defence sectors, the lack of suitable alternatives despite the considerable research and development activities over recent decades, the time necessary for qualification, certification and implementation of an alternative should one become available, the time necessary to comply with the airworthiness and safety regulatory requirements and the likelihood that substitution would not be possible within a shorter timeframe.

(15) Therefore, it is appropriate, as regards the use of dichromium tris(chromate) as limited in this Decision, to set the review period at seven years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(16) 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 languages of the Member States 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 that Member State.

(17) This Decision does not affect the obligation of the authorisation holder to ensure that the use of a substance 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, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible or the obligation of the employer under Articles 4(1) and 5 of Directive 2004/37/EC of the European Parliament and of the Council[3] 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, and to prevent workers' exposure to a risk to their health or safety. 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[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC[7], and Directive 2004/37/EC as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

(18) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[8] or Directive 2010/75/EU of the European Parliament and of the Council nor any obligation to comply[9] 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[10] or the environmental quality standards established in Directive 2008/105/EC of the European

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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).

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).

Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(19) Pursuant to Article 127(1) of the Withdrawal Agreement, Union law is applicable to and in the United Kingdom during the transition period unless otherwise provided in that Agreement. Under Article 126 of the Agreement, the transition period ends on 31 December 2020. It may, however, be extended for up to 1 or 2 years through a single decision adopted in accordance with Article 132 of the Withdrawal Agreement

(20) The addressee of this Decision is a legal entity established in the United Kingdom. Regardless of the period of validity pursuant to this Decision, the Decision can therefore only apply for the duration of that transition period.

(21) 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 dichromium tris(chromate) (EC No 246-356-2; CAS No 24613-89-6):

Authorisation number	Authorised use
REACH/20/10/0	Use in chemical conversion coating applications by aerospace and defence sector where any of the following key functionalities or properties is necessary for the intended use: corrosion resistance, active corrosion inhibition, adhesion promotion, chemical resistance, layer thickness, electrical properties

An authorisation for the use of dichromium tris(chromate) is not granted for use in chemical conversion coating applications by the aerospace and defence sector where none of the key functionalities or properties listed in the first paragraph is necessary for the intended use.

The authorisation is granted subject to the full application of the risk management measures and operational conditions described in the chemical safety report[12], as well as the conditions set out in Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 18.

2. The authorisation holder shall develop specific exposure scenarios for representative processes, operations and individual tasks covered by this authorisation, describing

[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).

[12] https://ec.europa.eu/docsroom/documents/31681

risk management measures and operational conditions representative for all sites at which the authorised use takes place, which can be used to control worker exposure to chromium (VI) and its emissions into the environment, in each of the specific scenarios. The exposure scenarios shall contain information on the exposure levels resulting from the implementation of those risk management measures and operational conditions.

The authorisation holder shall select the risk management measures described in the exposure scenarios in accordance with Article 5 of Directive 2004/37/EC. The selection shall be duly documented and justified and made available to the competent authorities upon request.

3. The specific exposure scenarios shall be made available to the downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 ("downstream users"), in an updated safety data sheet, by 8 July 2020. The authorisation holder and the downstream users shall apply the risk management measures and operational conditions included in the specific exposure scenarios without undue delay.

4. The authorisation holder shall verify and validate the specific exposure scenarios referred to in paragraph 2 at the latest on 8 October 2021 by making an analysis of tasks, using exposure and emission data measured by downstream users and related contextual information and by means of monitoring programmes of occupational exposure and environmental releases measurements referred to in paragraph 13, relating to all processes described for the authorised use. The verified and validated exposure scenarios shall be immediately made available to the downstream users.

5. The information to be made available to downstream users referred to in paragraphs 2 and 4 shall also include detailed guidance on how to select and apply risk management measures. That information shall be submitted by the authorisation holder and the downstream users, upon request, to the competent authority of the Member State where the authorised use takes place.

6. The downstream users shall implement best practices to reduce workplace exposure to dichromium tris(chromate) and emissions to the environment to as low a level as technically and practically feasible, including the use of closed systems and automation, whenever possible. Where this is not possible, the downstream users shall use local exhaust ventilation (LEV) systems that are appropriately designed, dimensioned, located and maintained to capture and remove dichromium tris(chromate).

Where closed systems and automation are not used, the non-use of LEV shall only be permitted in exceptional circumstances where the use of LEV is technically impossible and subject to the provision of appropriate justification. Information on LEV systems put in place in the installations where the authorised use takes place, as well as on their maintenance, shall be made available for inspection by the competent authority of the Member States.

7. The authorisation holder and the downstream users shall, without undue delay, equip baths with appropriately installed and correctly functioning extraction systems with a design efficiency of at least 90%.

8. The authorisation holder and the downstream users shall perform decanting and mixing of liquids in a dedicated area, with controlled access by trained workers, following procedures established based on appropriate task-based risk assessment.

9. The authorisation holder and the downstream users shall ensure that the area in which machining activities and bath treatment are undertaken is restricted either physically by means of barriers / signage or through strict procedure during the activity and for a specific time after the operation.

10. The authorisation holder and the downstream users shall use mechanical ventilation for machining activities in small work areas, unless the use of mechanical ventilation would create risks (e.g. local spark risk) or would otherwise not be technically and practically possible.

11. The authorisation holder and the downstream users shall implement effective cleaning practices in order to prevent surface contamination around treatment baths and other equipment, and in the vicinity where machining activities take place.

12. The authorisation holder and the downstream users shall check and test periodically LEV and respiratory personal equipment (RPE) (including fit testing of RPE), shall keep records of these periodical checks and tests and shall make them available for the competent authorities of the Member State where the use takes place. Workers shall be supervised and trained on the adequate use of personal protective equipment (PPE) and RPE and their medical fitness shall be examined annually.

13. The authorisation holder and the downstream users shall implement the following monitoring programmes for chromium(VI):

    (a) at least annual air monitoring programmes on occupational exposure to chromium (VI) in accordance with Article 5(5)(e) of Directive 2004/37/EC. The first measurements taken as part of these monitoring programmes shall be performed without delay and at the latest on 8 October 2020. Those programmes shall be based on relevant standard methodologies or protocols and be representative of:

        (i) the range of tasks undertaken where exposure to chromium is possible, including tasks involving process and maintenance workers;

        (ii) the operational conditions and risk management measures typical for each of these tasks;

        (iii) the number of workers potentially exposed;

    (b) at least annual monitoring programmes for chromium (VI) emissions to wastewater and air from local exhaust ventilation. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the operational conditions and risk management measures (such as waste water treatment systems, gaseous emission abatement techniques) used at the individual sites where relevant measurements are carried out.

14. The information gathered via the measurements referred to in paragraph 13 and related contextual information shall be used by the authorisation holder and its downstream users to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions in place and to introduce measures to further reduce exposure and emissions. The results of those measurements as well as any action taken following the review shall be documented and, upon request, be made available by the authorisation holder and its downstream

users to the competent authorities of the Member State where the authorised uses takes place.

15. The authorisation holder shall develop a report template for submission of monitoring data by downstream users in accordance with paragraph 16. The report template shall be supplied to the downstream users together with the updated safety data sheet referred to in paragraph 3.

16. The downstream users shall make available to the Agency the information from the monitoring programmes referred to in paragraph 13, including the contextual information associated with each set of measurements, for the first time by 8 April 2021, for transmission to the authorisation holder for the purpose of verifying and validating the specific exposure scenarios as referred to in paragraph 2 and afterwards for the preparation of the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

17. Following implementation by the downstream users of the validated risk management measures and operational conditions made available as part of the specific exposure scenarios in accordance with paragraph 4, those downstream users may reduce the frequency of measurements once they can clearly demonstrate to the competent authority of the Member State where the use takes place that exposure of humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions correspond to the exposure scenarios developed in accordance with paragraph 4 and function appropriately.

18. Where the frequency of the monitoring programme has been reduced in accordance with paragraph 17, any subsequent changes to the operational conditions or risk management measures that may affect the exposure at the site where the use takes place shall be documented. The authorisation holder and its downstream users shall assess the impact of such changes by monitoring, to demonstrate that exposure of workers and emissions to the environment continue to be reduced to as low a level as technically and practically possible.

Article 3

The downstream users shall include in the notification to the Agency pursuant to Article 66(1) of Regulation (EC) No 1907/2006 an explanation of the key functionalities or properties of dichromium tris(chromate) listed in Article 1 of this Decision which are necessary for their use, including a justification why such key functionalities are necessary for that use.

Article 4

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 January 2026.

2. The authorisation shall cease to be valid on 22 January 2026 in case the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 22 July 2024.

Article 5

In the event that a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006 is submitted, it shall include the following information:

(a) the information related to the exposure scenarios referred to in Article 2(2), (4) and the information referred to in Article 2(13) of this Decision. The exposure scenarios shall be for typical, representative downstream user sites, clearly describing the relationship between operational conditions, risk management measures and the resulting exposure levels, including detailed task descriptions and the description of how exposure occurs. A justification as to why the selected scenarios are representative and how the hierarchy of control principles is followed shall also be included;

(b) a refined assessment of the exposure of humans to chromium (VI) via the environment, as well as of the resulting risks. This assessment shall be carried out using a higher-tier exposure assessment model going beyond the default assumptions of the Agency's Guidance on Information Requirements and Chemical Safety Assessment[13] and those in the European Union System for the Evaluation of Substances (EUSES) model and shall make use of specific emission information. All reasonably foreseeable routes of exposure of humans via the environment, including the oral route, shall be included in the assessment.

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 Wesco Aircraft EMEA Limited, Lawrence House, Riverside drive, BD19 4DH, Cleckheaton, West Yorkshire, United Kingdom.

Done at Brussels, 8.4.2020

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION

[13] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment