



Brussels, 29.10.2019
C(2019) 7683 final

COMMISSION IMPLEMENTING DECISION

of 29.10.2019

**partially granting an authorisation for a use of potassium dichromate 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/EC¹, 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 laid down in Article 56(1)(a) of that Regulation.
- (2) On 17 March 2016, Haas Group International SCM Ltd ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of potassium dichromate for sealing after anodizing applications by the aerospace sector.
- (3) On 17 May 2017, a legal entity change was notified to the European Chemicals Agency ('the Agency') pursuant to which the applicant and several other legal entities based in the United Kingdom were consolidated into a single legal entity, Wesco Aircraft EMEA Limited.
- (4) On 15 December 2017, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the Agency² on the application pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006. Those opinions reflected the legal entity change.
- (5) In its opinion, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of potassium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore potassium dichromate 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) of the same Regulation, its Article 60(2) does not apply to that substance,

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/33c0c3b5-e157-ac83-cd50-fd0e29e0e388>

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

- (6) 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 the risk to workers and to the general population that could potentially be exposed via the environment.
- (7) RAC concluded that there are significant uncertainties regarding worker exposure due to the lack of measured exposure data for all worker contributing scenarios and it also considered that the lack of information on the relationship between operational conditions and risk management measures and exposure levels is a significant source of uncertainty. Nevertheless, the Commission considers that those uncertainties did not prevent SEAC from further analysing the application.
- (8) RAC further concluded that uncertainties also exist in the assessment of exposure of the general population to the substance, via the environment, at the local scale, as regards both exposure through inhalation and oral exposure. Furthermore, RAC did not fully agree with the applicant's statement that wastewater releases are negligible.
- (9) 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 the uncertainties in the assessment of risks to workers and to the general population via the environment, RAC recommended additional conditions that address these issues. The Commission, having evaluated RAC's assessment, concurs with its conclusions.
- (10) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of potassium dichromate covered by the application outweigh the risk to human health and the environment arising from that use. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.
- (11) 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.
- (12) In its opinion, SEAC concluded that there are no suitable alternative substances or technologies. Due to the generic approach in the analysis of alternatives, SEAC could not exclude possible uncertainty with regard to the technical feasibility of alternatives for some specific utilisations falling within the scope of the use covered by the

application. However, SEAC took note of the complex airworthiness and approval process and in particular the time necessary for qualification and certification for implementing alternatives. The Commission concurs with SEAC conclusion and, given the broad scope of the use applied for, considers 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 discharged its burden of proof in demonstrating the absence of suitable alternatives only with regard to such limited scope of the use. Consequently, the description of the authorised use should be limited by referring it to uses where the key functionalities of corrosion resistance or corrosion inhibition (i.e. self-healing) are necessary for the intended use.

- (13) 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.
- (14) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of potassium dichromate, as limited in this Decision, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report, as well as the conditions set out in this Decision are fully applied. The authorisation should not be granted for the part of use where the specified key functionalities are not necessary.
- (15) 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.
- (16) 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 which are required for their use.
- (17) 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 Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and, in particular, the uncertainties relating to the exposure assessment, the uncertainties with regard to the appropriateness and effectiveness of the operational conditions and risk management measures in limiting the risk to workers, the conclusion that the socio-economic benefits of the continued use significantly outweigh the risk, the long investment cycle of the applicant and the long service lifetime of the aircraft, the expected time needed for an extensive qualification, certification and implementation of a potentially suitable alternative according to the airworthiness requirements as well as the uncertainty as regards the exact time when such an alternative might become available.
- (18) Therefore, it is appropriate to set a review period of seven years from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (19) 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.

- (20) 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 the Union law in the area of health and safety 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.
- (21) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC⁸ or 2010/75/EU⁹ of the European Parliament and of the Council, or 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 legislation, as those may include further or more onerous requirements.

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).

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).

- (22) On 29 March 2017, the United Kingdom submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. The Treaties will cease to apply to the United Kingdom from the date of entry into force of a withdrawal agreement or, failing that, two years after the notification, unless the European Council, in agreement with the United Kingdom, unanimously decides to extend that period.
- (23) This Decision is addressed to a legal entity established in the United Kingdom. Unless otherwise provided for in a withdrawal agreement, this Decision can therefore only apply to that addressee until the Treaties cease to apply to the United Kingdom notwithstanding the end of the validity laid down in this Decision.
- (24) 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 potassium dichromate (EC No 231-906-6; CAS No 7778-50-9):

Authorisation number	Authorised use
REACH/19/31/0	Sealing after anodizing applications by the aerospace sector, where the key functionalities of corrosion resistance or corrosion inhibition are necessary for the intended use

An authorisation for the use of potassium dichromate is not granted for sealing after anodizing applications by the aerospace sector where none of the key functionalities listed in the first subparagraph are 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 report¹², and once available, subject to those described in the specific exposure scenarios to be developed pursuant to Article 2, as well as the conditions laid down in Article 2.

In addition, from 29 January 2020, the authorisation shall be subject to the risk management measures and operational conditions described in the specific exposure scenarios to be developed pursuant to Article 2.

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 15.

¹² <https://ec.europa.eu/docsroom/documents/27002>

2. The authorisation holder shall develop specific exposure scenarios for representative processes, operations and individual tasks describing risk management measures and operational conditions representative for all sites at which the authorised use takes place, which are used to control worker exposure to chromium (VI) and its emissions to the environment, in each of the specific scenarios, and providing information on the exposure levels resulting from the implementation of the referred 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. Those 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, at the latest on 29 January 2020..
3. The exposure scenarios to be developed by the authorisation holder as referred to in paragraph 2 shall be validated and verified by it at the latest on 29 April 2021 by making an analysis of tasks, using exposure and emission data measured by downstream users and related contextual information and by means of representative programmes of occupational exposure and environmental releases measurements, relating to all processes described associated to the authorised use.
4. The specific exposure scenarios to be made available to downstream users as referred to in paragraph 2 shall also include detailed guidance on how to select and apply risk management measures. That information shall be submitted, upon request, to the competent authorities of the Member State where the authorised use takes place.
5. The downstream users shall implement best practices to reduce workplace exposure to potassium dichromate 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 and in particular for tasks involving decanting and weighting of solids (corresponding to the worker contributing scenario in the chemical safety report referred to in Article 1). 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 potassium dichromate. Furthermore, the area in which activities with solid chromates are conducted shall be restricted either physically by means of barriers or through strict procedure during the activity and for a specified time after the operation.
6. Mechanical ventilation shall be used for machining activities in small work areas (worker contribution scenario 13 in the chemical safety report referred to in Article 1), except in cases where mechanical ventilation would introduce risks (e.g. local spark risk) or would otherwise not be technically and practically possible.
7. Effective cleaning practices shall be implemented to prevent surface contamination around treatment baths and other equipment, in the vicinity where machining activities take place, and where solid chromates are handled.
8. LEV and personal respiratory equipment (RPE) shall be checked and tested periodically (including fit testing of RPE) and records of these periodical checks and tests shall be kept and made available for national competent authorities.

9. Whenever technically and practically possible, activities under worker contributing scenario 15 in the chemical safety report referred to in Article 1 (waste management) shall be conducted under appropriately designed and installed LEV.
10. The authorisation holder and its downstream users shall implement the following monitoring programmes for chromium (VI):
 - (a) at least annual air monitoring programmes in accordance with Article 5(5)(e) of Directive 2004/37/EC. The first measurements shall be performed without delay and at the latest by 29 April 2020. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the range of tasks undertaken where exposure to chromium is possible, including tasks involving process and maintenance workers, the operational conditions and risk management measures typical for each of these tasks and 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 measurements are carried out.
11. The authorisation holder and the downstream users shall use the information gathered via the measurements referred to in paragraph 10 and related contextual information to regularly review the 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 of any action taken following the review shall be documented and be made available by the authorisation holder and their downstream users, upon request, to the competent authorities of the Member State where the authorised uses take place.
12. The authorisation holder shall draw up recommendations and guidelines to assist downstream users in conducting the monitoring programmes measurements referred to in paragraph 10 and shall develop a report template for submission of monitoring data by downstream users according to paragraph 13. The report template shall be supplied to the downstream users together with the updated safety data sheet referred to in paragraph 2.
13. The downstream users shall make available to the Agency the information collected in accordance with paragraph 10, including the contextual information associated to each set of measurements, in the format of the template referred in paragraph 12, for the first time by 29 October 2020, for transmission to the authorisation holder for the purpose of validating the exposure scenarios as well as towards the review report referred to in Article 61(1) of that Regulation. That information shall also be maintained and be made available by the authorisation holder and downstream users, upon request, to the competent authorities of the Member State where the authorised use takes place.
14. Following implementation of the revised specific risk management measures and operational conditions in accordance with paragraph 3, 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 to 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 3 and function appropriately.

15. Where the frequency of the monitoring programme has been reduced in accordance with paragraph 14, 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) an explanation of the key functionalities of potassium dichromate listed in Article 1 which are necessary for their use.

Article 4

1. The review period shall expire on 21 September 2024.
2. The authorisation shall cease to be valid on 21 September 2024 unless a review report has been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 21 March 2023.

Article 5

In the event that a review report is submitted, it shall include the following information:

- (a) the information referred to in Article 2(2), (3) and (10);
- (b) a refined assessment of the exposure of humans to chromium (VI) via the environment, as well as of the resulting risks. That assessment shall be carried out using a higher-tier exposure assessment model going beyond the default assumptions in the Guidance on Information Requirements and Chemical Safety Assessment¹³ and 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

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.

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

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, 29.10.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

