EUROPEAN
COMMISSION

Brussels, 22.10.2019
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COMMISSION IMPLEMENTING DECISION

of 22.10.2019

partially granting an authorisation for certain uses of sodium chromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Aviall Services Inc. and Wesco Aircraft EMEA Limited)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(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[1], and in particular Article 64(8) thereof,

Whereas:

(1) Sodium chromate is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement laid down in Article 56(1)(a) of that Regulation.

(2) On 4 March 2016, Aviall Services Inc. and Haas Group International SCM Ltd ('the applicants') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of sodium chromate in the formulation of mixtures for sealing after anodizing, chemical conversion coating, pickling and etching applications by the aerospace sector ('use 1'), and for sealing after anodizing, chemical conversion coating, pickling and etching applications by aerospace sector ('use 2').

(3) On 17 May 2017, a legal entity change was notified to the European Chemicals Agency (‘the Agency’) pursuant to which the application was transferred from the original applicant Haas Group International SCM Ltd to 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 Agency[2] on the application pursuant to the second subparagraph of Article 64(5) of

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

[2] https://echa.europa.eu/documents/10162/8d782116-35c0-0384-294b-2f5974e7157f
https://echa.europa.eu/documents/10162/77b85e28-5d15-0541-2cb8-f73fb75f8b65

Regulation (EC) No 1907/2006. The legal entity change was reflected in the RAC and SEAC opinions.

(5) In its opinions, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of sodium chromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore sodium 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. 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.

(6) In its opinions on both uses, 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.

(7) Concerning both uses, RAC concluded that there are uncertainties in the exposure assessment due to the limited availability of measured exposure data and the lack of contextual information. As regards use 1, the uncertainties could be reduced by providing more measured data and more detailed information on the operational conditions and risk management measures. As regards use 2, the uncertainties inherent in a qualitative and modelled exposure estimate are particularly relevant for the machining operations on metallic surfaces.

(8) Concerning both uses, RAC acknowledged that release to air of chromium (VI) is likely to be low due to the low volatility of sodium chromate and modern abatement technology with high efficiency. RAC however concluded that uncertainties exist in the assessment of exposure of members of general population who could potentially be exposed via the environment as the assessment of emissions to air and exposure of members of general population through inhalation is based on modelled data in the absence of measured data. Furthermore, RAC did not fully agree with the applicants' statement that wastewater releases are negligible and concluded that the absence of quantitative exposure estimate for the oral route introduces uncertainties.

(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 and monitoring arrangements that address these issues. The Commission, having evaluated RAC's assessment, concurs with its conclusions.

(10) In its opinions on uses 1 and 2, SEAC concluded that the overall socio-economic benefits arising from those uses outweigh the risk to human health. 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 opinions, 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. The Commission concurs with SEAC conclusion and, given the broad scope of the use applied for, considers necessary to limit the description of use 2 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 applicants discharged their burden of proof in demonstrating the absence of suitable alternatives only with regard to such limited scope of the use.

(13) Consequently, the description of use 2 should be limited by referring it to uses where any of the following key functionalities or properties is necessary for the intended use: for the pickling/etching process - etch rate, intergranular attack/end grain pitting, surface contamination, fatigue testing, tensile testing, surface roughness, impact to shot peen compressive layer; and for the chemical conversion coating and sealing after anodising process - corrosion resistance, active corrosion inhibition, adhesion promotion, chemical resistance, layer thickness, electrical properties.

(14) As regards both uses, the Commission considers that the applicants have demonstrated that no potential alternatives provide the level of technical performance functionally necessary for the uses applied for.

(15) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise use 1 and use 2 of sodium chromate 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 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 part of use where the specified key functionalities are not necessary for the intended use.

(16) 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.

(17) Furthermore, in order to facilitate the enforcement of this Decision, the Commission considers necessary to require the authorisation holders 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.

(18) In its opinions on both uses, 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 the RAC and SEAC assessments, and in particular, the uncertainties related to the exposure assessment, the concerns related to the appropriateness and effectiveness of the risk management measures and operational conditions, on the one hand, and the recommended additional conditions and monitoring arrangements, the conclusion that the socio-economic benefits of continued use significantly outweigh the risk, the applicants' long investment cycle as well as the long service life of the aircraft, the time needed for an extensive testing, certification and industrialisation of a potentially suitable alternative according to the airworthiness requirements and the uncertainty as regards the time when one might become available, on the other hand. Furthermore, since use 1 serves no other purpose than to allow for the formulation of the mixtures required for use 2 and has no separate functionality, the analysis of alternatives and the socio-economic analysis cover both uses simultaneously.

(19) It is therefore appropriate, as regards both uses, to set a review period of seven years from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(20) 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 uses take place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require the authorisation holders to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State concerned.

(21) This Decision does not affect the obligation of the authorisation holders 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 holders 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[3], 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[4], 92/85/EEC[5], 94/33/EC[6] and

[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).

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.

(22) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC[8] or 2010/75/EU[9] 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[10] or established in Directive 2008/105/EC of the European Parliament and of the Council[11]. 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.

(23) 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.

(24) This Decision is addressed to a legal entity established in the United Kingdom. Unless otherwise provided for in a withdrawal agreement, the 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.

(25) 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 sodium chromate (EC No 231-889-5; CAS No 7775-11-3):

Authorisation number	Authorisation holder	Authorised use
REACH/19/32/0	Aviall Services Inc.	Formulation of mixtures for sealing

[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).

REACH/19/32/1	Wesco Aircraft EMEA Limited	after anodizing, chemical conversion coating, pickling and etching applications by the aerospace sector
REACH/19/32/2 REACH/19/32/3	Aviall Services Inc. Wesco Aircraft EMEA Limited	Sealing after anodizing, chemical conversion coating, pickling and etching applications by the aerospace sector, where any of the following key functionalities or properties is necessary for the intended use: for the pickling/etching process - etch rate, intergranular attack/end grain pitting, surface contamination, fatigue testing, tensile testing, surface roughness, impact to shot peen compressive layer; and for the chemical conversion coating and sealing after anodising process - corrosion resistance, active corrosion inhibition, adhesion promotion, chemical resistance, layer thickness, electrical properties

An authorisation for the use of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by the aerospace sector is not granted for this use where none of the key functionalities listed in the first subparagraph 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 to the conditions laid down in Articles 2 and 4.

In addition, from 24 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 referred to in paragraphs 2 to 15.

2. The authorisation holders shall develop, without undue delay, specific exposure scenarios for representative processes, operations and individual tasks describing risk management measures and operational conditions which are applied in all sites where the authorised uses take place and which are used to control worker exposure to chromium (VI) and its emissions to the environment. The specific exposure scenarios shall include detailed descriptions of tasks and of how they are to be performed and shall contain information on the exposure levels resulting from the implementation of the risk management measures and operational conditions.

[12] https://ec.europa.eu/docsroom/documents/27004/

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

4. 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, at the latest on 24 January 2020.

5. The authorisation holders shall validate and verify the specific exposure scenarios at the latest on 24 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 referred to in paragraph 11, as regards all the processes related to the authorised uses.

6. Where the validation and verification indicates that exposure and releases are not reduced to a level as low as technically and practically possible, the authorisation holders shall revise the exposure scenarios in accordance with paragraph 2 and, without undue delay, make the revised exposure scenarios available to the downstream users, in the updated safety data sheet referred to in paragraph 4.

7. The specific exposure scenarios to be made available to downstream users shall 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 States where an authorised use takes place.

8. Downstream users shall implement best practices to reduce workplace exposure to sodium chromate and its emissions to the environment to as low a level as technically and practically feasible, including by using closed systems and automation, when possible. Closed systems and automation shall, where possible, be used for tasks involving decanting and weighing of solids, corresponding to worker contributing scenario 3 in the chemical safety report referred to in Article 1 for the use bearing authorisation numbers REACH/19/32/2 and REACH/19/32/3).

   Where use of closed systems and automation is not possible, downstream users shall use appropriately designed and installed local exhaust ventilation (LEV) systems that are dimensioned, located and maintained so as to capture and remove sodium chromate. Where closed systems and automation are not used downstream users shall be permitted not to use LEV only exceptionally, where its use is technically impossible. Information on LEV systems put in place in the installations where the authorised uses take place, as well as of their maintenance, shall be made available to the competent authorities of Member States.

   Where respiratory protective equipment (RPE) is needed to control exposure to sodium chromate, the authorisation holders and the downstream users shall use it in accordance with standard procedures for use and maintenance, including procedures for fit testing of RPE masks, applied in accordance with relevant standards.

9. Where technically and practically possible, and taking into account the obligation to provide a justification for not using LEV set out in paragraph 8, waste management activities (corresponding to worker contributing scenarios 10 and 17 of the chemical safety reports of the uses bearing authorisation numbers REACH/19/32/2 and REACH/19/32/3), shall be conducted under LEV.

10. The authorisation holders and the downstream users shall restrict the area in which activities involving the use of solid chromates are conducted either physically by means of barriers or by means of a strict procedure during the activity and for a specified time thereafter.

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

(a) air monitoring programmes on occupational exposure to chromium (VI) in accordance with Article 5(5)(e) of Directive 2004/37/EC. The first measurements shall be performed without delay and at the latest on 24 April 2020. Those programmes shall:

– take place annually;

– be based on relevant standard methodologies or protocols;

– be representative of the range of tasks undertaken where exposure to chromium (VI) is possible, including tasks involving process and maintenance workers, of the operational conditions and risk management measures typical for each of these tasks, and of the number of workers potentially exposed;

(ii) annual monitoring programmes for chromium (VI) emissions to wastewater and air from LEV. 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. The programmes shall be carried out at least once per year.

12. The authorisation holders and downstream users shall use the information gathered via the measurements referred to in paragraph 11 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 holders and their downstream users, upon request, to the competent authorities of the Member State where the authorised uses take place.

13. The authorisation holders shall draw up recommendations and guidelines to assist downstream users in conducting the monitoring programmes measurements referred to in paragraph 11 and shall develop a report template for submission of monitoring data by downstream users according to paragraph 14. The report template shall be supplied to the downstream users together with the updated safety data sheet referred to in paragraph 4.

14. The downstream users shall make available to the Agency the information collected according to paragraph 11, including the contextual information related to each set of measurements, in the format of the template referred to in paragraph 13, for the first time on 24 October 2020, for transmission to the authorisation holders for the purpose of validating the exposure scenarios and of preparing the review report according to Article 61(1) of Regulation (EC) No 1907/2006. The authorisation holders and the downstream users shall maintain and make available that information to the competent authorities of the Member States where the authorised uses take place, upon request.

15. Having implemented the revised risk management measures and operational conditions, the downstream users may reduce the frequency of measurements referred to in paragraph 11, once they can 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 revised exposure scenarios and function appropriately.

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 sodium chromate listed in Article 1 which are necessary for their use.

Article 4

The authorisations bearing authorisation numbers REACH/19/32/2 and REACH/19/32/3 shall be subject to the following specific conditions:

(a) mechanical ventilation shall be used for tasks involving machining activities in small areas, unless this would introduce risks or is technically and practically not possible;

(b) effective cleaning practices shall be implemented to prevent surface contamination around treatment baths where machining activities take place and where solid chromates are handled;

(c) measures shall be taken to ensure that pickling and etching baths remain below boiling point at all times.

Article 5

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 6

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

(a) the information referred to in paragraphs (2), (3) and (11) of Article 2;

(b) a refined assessment of the exposure to chromium (VI) of humans via the environment and 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 Assessment[13] 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

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

humans via the environment, including the oral route, shall be included in the assessment.

Article 7

Upon request of the competent authority of the Member States where the authorised uses take place, the authorisation holders 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 8

This Decision is addressed to:

1. Aviall Services Inc. Schillingweg 40, 2153PL, Nieuw-Vennep, Noord-Holland, The Netherlands;

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

Done at Brussels, 22.10.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION