EUROPEAN
COMMISSION

Brussels, 15.4.2020
C(2020) 2090 final

COMMISSION IMPLEMENTING DECISION

of 15.4.2020

partially granting an authorisation for certain uses of dichromium tris(chromate) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Henkel AG & Co. KGaA and and Henkel Global Supply Chain B.V.)

(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) Dichromium tris(chromate) 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 19 November 2015, Henkel AG & Co. KGaA and Henkel Global Supply Chain B.V. ('the applicants') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the uses of dichromium tris(chromate) in the formulation of mixtures ('use 1') and for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites and sealings of anodic films ('use 2'). As the composites and anodic films may have non-metallic areas the use should be referred to as the use "surface treatment of metals (such as aluminium, steel, zinc, magnesium, titanium, alloys), composites and sealings of anodic films".

(3) On 13 December 2016, 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, 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 dichromium tris(chromate) in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that 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. Pursuant to Article 60(3)(a) of that Regulation, its Article 60(2) does not apply to that

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

[2] https://echa.europa.eu/documents/10162/00d5b118-ea23-c76a-7e69-b70f5b764339 https://echa.europa.eu/documents/10162/6f27e74d-8aef-e8e9-4a85-429e1c7e5c05

substance, and therefore an authorisation may only be granted on the basis of 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 not appropriate and effective in limiting the risks to workers.

(6) RAC concluded that there are significant uncertainties regarding worker exposure due to limited availability of measured exposure data. According to RAC there was a lack of clear link between the type of surface treatment, the operational conditions and risk management measures described in the application and the claimed exposure levels for specific tasks and sites, preventing RAC from further evaluation. The difficulty to determine the claimed exposure levels associated to the different tasks is particularly relevant to use 2, where, in addition to bath immersion, different activities including spraying, rolling, brushing, 'penstick' application and machining operations are covered, and the applicants have not been able to fully assess the combined exposure related to all those tasks. RAC therefore proposed to use the applicants estimate of a maximum combined individual worker exposure level as the basis of further analysis by SEAC.

(7) 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, particularly regarding emission of chromium (VI) via wastewater. This is particularly relevant as regards oral exposure via drinking water. However, RAC considered the assessment of risks to the general population via the environment provided by the applicants to be sufficient for further analysis by SEAC, noting that the applicants' approach is based on assumptions that are likely to overestimate the risks to the general population. Regional exposure, although estimated by the applicants, was not considered relevant by RAC due to transformation of chromium (VI) to non-carcinogenic chromium (III) that will occur rapidly under most environmental conditions.

(8) 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 and recommendations.

(9) In its opinions on uses 1 and 2, SEAC concluded that the overall socio-economic benefits outweigh the risk to human health arising from those uses. Although SEAC identified uncertainties in the applicants' assessment, it considered the information provided by the applicants sufficient to clearly conclude.

(10) Despite the uncertainties identified by RAC and SEAC and on the basis of their opinions, the Commission concludes that socio-economic benefits from uses 1 and 2 outweigh the risk to human health.

(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 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 on use 1, considering that dichromium tris(chromate) has no independent function at the stage of formulation and consequently an assessment of the feasibility of alternatives for that use is irrelevant, SEAC concluded that there are no suitable alternative substances or technologies. Since the sole purpose of use 1 is to allow for the formulation of the mixtures required for use 2, SEAC considered necessary to limit the use accordingly. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.

(13) In its opinion on use 2, SEAC concluded that there are no suitable alternative substances or technologies. In order to address the uncertainties due to the broadly defined scope of the intended use, SEAC considered necessary to limit the description of the use by referring it to certain surface treatment processes in which certain key functionalities are required in the aerospace sector. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and 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.

(14) As regards all 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, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of dichromium tris(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, as well as the conditions set out in this Decision, are fully applied. The authorisation should not be granted for the part of use 2 where the specified key functionalities are not required for a particular surface treatment process.

(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 listed in the Annex which are

required 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).

(18) In its opinions, 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 both uses covered by the application. The Commission concurs with that recommendation, taking into account the relevant elements from RAC and SEAC assessments, and in particular, the fact that dichromium tris(chromate) has no independent function at the stage of formulation and that any substitution for use 1 is interlinked with the substitution of use 2, the concerns related to the appropriateness and effectiveness of the risk management measures and operational conditions and the recommended strict additional conditions and monitoring arrangements to address those concerns, the likelihood that substitution would not be possible within a shorter timeframe despite the past and the ongoing research and development activities, the time necessary to implement and industrialise possible alternatives, should they become available, including the time necessary for their qualification and their regulatory certification in relation to safety and airworthiness as well as the expected negative social and economic consequences in case of no authorisation.

(19) Therefore, for both uses, 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.

(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 brief summary of those risk management measures and operational conditions in an official language of the Member States concerned.

(21) This Decision does not affect the obligation of the authorisation holders to ensure that the uses do 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, 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 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) 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 dichromium tris(chromate) (EC No 246-356-2; CAS No 24613-89-6):

Authorisation number	Authorisation holder	Authorised use
REACH/20/1/0 REACH/20/1/1	Henkel AG & Co. KGaA Henkel Global Supply Chain B.V.	Formulation of mixtures intended exclusively for uses REACH/20/1/2 and REACH/20/1/3)
REACH/20/1/2 REACH/20/1/3	Henkel AG & Co. KGaA Henkel Global Supply Chain B.V.	Surface treatment of metals (such as aluminium, steel, zinc, magnesium, titanium, alloys), composites and sealings of anodic films for the aerospace sector in surface treatment processes in which any of the key functionalities listed in the Annex is required

[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).

An authorisation for the use of dichromium tris(chromate) is not granted for surface treatment of metals composites and sealings of anodic films for the aerospace sector where none of the key functionalities listed in the Annex is required for a particular surface treatment process.

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.

In addition, from 15 July 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 authorisations shall be subject to the conditions set out in paragraphs 2 to 13.

2. The authorisation holders shall develop specific exposure scenarios for representative processes, operations and individual tasks (including, for example, automatic versus manual systems and open versus closed systems and combinations thereof), describing risk management measures and operational conditions applied in all sites at which the authorised uses take place and which are used to control worker exposure to chromium (VI) and its emissions to 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 holders 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 of the Member State where the authorised uses take place 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 15 July 2020.

3. The exposure scenarios to be developed by the authorisation holders as referred to in paragraph 2 shall be validated and verified by them at the latest on 15 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 representative programmes of occupational exposure and environmental releases measurements referred to in paragraph 9, relating to all processes described associated to the uses applied for. The validated and verified exposure scenarios shall be immediately made available to the downstream users.

4. The information to be made available to the downstream users as referred to in paragraph 2 and 3 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 uses take place.

5. 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

[12] http://ec.europa.eu/DocsRoom/documents/20666

automation, whenever possible, and in particular the case 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/20/1/2 to REACH/20/1/3).

Where the use of closed systems is not possible, the authorization holders and 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 authorisation holder and its downstream users shall be permitted not to use LEV only exceptionally, where its use is technically impossible and subject to the provision of appropriate justification. 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 authority of the Member State where the authorised uses take place.

6. Where respiratory protective equipment (RPE) is needed to control exposure to dichromium tris(chromate), it shall be used in accordance with standard procedures for use and maintenance, including procedures for fit testing of RPE masks, applied in accordance with relevant standards.

7. Appropriate standard operating procedures shall be developed and implemented to minimise release of dust into the air during the preparation, transfer and storage of empty bags, filters and other process waste, in accordance with the hierarchy of control provisions set out in Article 5 of Directive 2004/37/EC.

8. Whenever technically and practically possible and taking into account the obligation to provide a justification for non-use of LEV set out in the second subparagraph of paragraph 5, waste management activities (corresponding to worker contributing scenarios 11 and 27 of the chemical safety report referred to in Article 1 shall be conducted under appropriately designed and installed LEV.

9. 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 15 October 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, maintenance and machining operations, the operational conditions and risk management measures typical for each of those tasks, and the number of workers potentially exposed;

   (b) 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.

10. The authorisation holders and the downstream users shall use the information gathered via the measurements referred to in paragraph 9 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 the downstream users, upon request, to the competent authorities of the Member State where the authorised uses take place.

11. The authorisation holders shall draw up recommendations and guidelines to assist downstream users in conducting the monitoring programmes measurements referred to in paragraph 9 and shall develop a report template for submission of monitoring data by downstream users according to paragraph 12. The report template shall be supplied to the downstream users together with the updated safety data sheet referred to in the third subparagraph of paragraph 2.

12. The downstream users shall make available to the Agency the information collected in accordance with paragraph 9, including the contextual information related to each set of measurements, in the format of the template referred in paragraph 11, for the first time by 15 April 2021, for transmission to the authorisation holders for the purpose of validating the exposure scenarios as well as towards the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

13. Following implementation of the revised risk management measures and operational conditions made available in accordance with paragraph 3 by the authorisation holders to the downstream users, those downstream users may reduce the frequency of measurements, once they clearly demonstrate to the competent authority of the Member State where the uses take 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 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 dichromium (tris)chromate listed in the Annex which are required 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 with regard to the authorisation holders who have not submitted the review report refered to in Article 61(1) of Regulation (EC) No 1907/2006 by 22 July 2024.

Article 5

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

(a) the information referred to in Article 2(2), including detailed guidance on how to select and apply risk management measures as per Article 2(4) and the information referred to in Article 2(9) 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 of 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 humans via the environment, including the oral route, shall be included in the assessment.

Article 6

The authorisation holders shall submit, upon request, to the competent authority of the Member State where the authorised uses take 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.

Article 7

This Decision is addressed to:

1. Henkel AG & Co. KGaA., Henkelstrasse 67, 40191 Düsseldorf, North-Rhine Westfalia, Germany;
2. Henkel Global Supply Chain B.V., Gustav Mahlerlaan 2970, 1081 LA Amsterdam, Netherlands.

Done at Brussels, 15.4.2020

For the Commission
Thierry BRETON
Member of the Commission

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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