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COMMISSION IMPLEMENTING DECISION

of 14.4.2020

partially granting an authorisation for certain uses of potassium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Gentrochema BV)

(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,

Whereas:

(1) Potassium dichromate 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 9 February 2016, Gentrochema BV ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of potassium dichromate in the formulation of mixtures of potassium dichromate for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites and sealings of anodic films ('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 uses 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 17 March 2017, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] ("the Agency") on the application, pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006. RAC and SEAC confirmed the applicant’s declaration that the application is an application made by a subsequent applicant in accordance with Article 63(1) of Regulation (EC) No 1907/2006, and that the applicant has demonstrated that it had permission to refer to the relevant parts of the application for authorisation for certain uses of potassium

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

[2] https://echa.europa.eu/documents/10162/40b52c6b-4825-a0a8-ad36-35fd966b3dd1 https://echa.europa.eu/documents/10162/f69980ed-2451-1575-aefd-669e3c3ef6dd

dichromate made by Brenntag UK Ltd. and others (the 'previous application'). RAC and SEAC noted that the justifications for the opinions on the previous application are valid for the application of Gentrochema BV with regard to the same uses. RAC and SEAC took note of specific information submitted by the applicant in response to their requests for information. That information indicates that the annual tonnage of the substance used and the number of sites covered by the application for authorisation are substantially lower than those described in the previous application. Consequently, both the estimated health impact and the economic and social impact of uses 1 and 2 than can be attributed to the applicant, were overestimated in the assessment made based on the previous application.

(4) In its opinions, 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 Regulation (EC) No 1907/2006. 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.

(5) 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 risks to workers. RAC concluded that there are significant uncertainties regarding worker exposure due to limited availability of measured exposure data. It further concluded that a prevalent lack of contextual information made it difficult to establish a link between 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 as regards use 2 where, in addition to bath immersion, different activities including spraying, rolling, brushing, 'penstick' application and machining operations are covered and the applicant has not been able to fully assess the combined exposure related to all of them. RAC therefore proposed to use the applicant estimate of a maximum combined individual worker exposure level as the basis of further analyses by SEAC.

(6) RAC further concluded that there are uncertainties in the assessment of exposure of the general population to potassium dichromate 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 that the provided assessment of risks to man via the environment was sufficient for further analysis by SEAC, noting that the approach by the applicant is based on assumptions that are likely to overestimate the risks to the general population. Regional exposure, although estimated by the applicant, 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.

(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 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.

(8) 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 and that there are no suitable alternative substances or technologies that are technically and economically feasible for the applicant and its downstream users. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.

(9) 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.

(10) Regarding use 1, since its sole purpose is to allow for the formulation of the mixtures required for use 2 and since potassium dichromate has no independent function at the stage of formulation, SEAC considered necessary to limit the use accordingly and recommended additional conditions. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.

(11) Regarding use 2, in order to address the uncertainties due to the broadly described scope of the use and to ensure consistency with the scope of the assessment provided in the application, 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, 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.

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

(13) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of potassium dichromate 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. 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.

(14) 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.

(15) 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 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).

(16) 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 uses 1 and 2. The Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and in particular the conclusion that potassium dichromate has no independent function at the stage of formulation and that any substitution for use 1 is linked to the substitution of use 2, the concerns related to the appropriateness and effectivenss of the risk management measures and operational conditions and the recommended additional conditions and monitoring arrangements to address those concerns, the likelihood that substitution would not be possible within a shorter timeframe despite research and development activities, the time necessary to implement and industrialise possible alternatives, should they become available, including the time necessary for the qualification and the regulatory certification in relation to safety and airworthiness as well as the expected negative social and economic consequences in case of refusal to grant an authorisation.

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

(18) 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.

(19) 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 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 and 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

[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).

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 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.

(20) 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.

(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 uses of potassium dichromate (EC No 231-906-6; CAS No 7778-50-9):

Authorisation number	Authorised use
REACH/20/2/0	Formulation of mixtures for surface treatment of metals (such as aluminium, steel, zinc, magnesium, titanium, alloys), composites and sealings of anodic films intended exclusively for use REACH/20/2/1

[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).

REACH/20/2/1	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

An authorisation for the use of potassium dichromate 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 risk management measures and operational conditions described in the chemical safety report[12] as well as to the conditions laid down in Article 2.

In addition, from 14 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 authorisation shall be subject to the conditions set out in paragraphs 2 to 13.

2. The authorisation holder shall develop, within the timeframe set out in paragraph 3, 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 where the authorised uses take place and which are used to control worker exposure to chromium (VI) and its emissions to the environment.

   The exposure scenarios shall contain information on the exposure levels resulting from the implementation of the risk management measures and operational conditions.

   The authorisation holder shall select the risk management measures for the 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.

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, at the latest on 14 July 2020.

4. The authorisation holder shall validate and verify the specific exposure scenarios at the latest on 14 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, as regards all the processes related to the authorised uses. The validated and verified exposure scenarios shall be immediately made available to the downstream users.

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5. 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 authority of the Member State where the authorised uses take place.

6. The downstream users shall implement best practices to reduce workplace exposure to potassium dichromate 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 as regards use number REACH/20/2/1.

   Where use of closed systems and automation is not possible, the authorisation holder and the downstream users shall use local exhaust ventilation (LEV) systems that are designed, dimensioned, located and maintained so as to capture and remove potassium dichromate. Where closed systems and automation are not used, the authorisation holder and the 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 authorities of the Member States where the authorised uses take place.

7. Where respiratory protective equipment (RPE) is needed to control exposure to potassium dichromate, 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.

8. The authorisation holder and the downstream users shall develop and implement standard operational procedures 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.

9. The authorisation holder 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 14 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, of the operational conditions and risk management measures typical for each of these tasks, and of 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 holder 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 authorisation holder and the downstream users shall document the results of those measurements as well as of any action taken following the review and shall make them available, upon request, to the competent authorities of the Member States where an authorised use takes place.

11. The authorisation holder 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 paragraph 3.

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 14 April 2021, for transmission to the authorisation holder for the purpose of validating the specific exposure scenarios and of preparing the review report.

13. Having implemented the risk management measures and operational conditions described in specific exposure scenarios according to paragraph 4, the downstream users may reduce the frequency of measurements 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 specific 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 potassium dichromate 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 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

If the authorisation holder 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(5) 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

Upon request, the authorisation holder shall submit a brief 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 Gentrochema BV, Esdoornlaan 19a, 4254 AT Sleeuwijk, Netherlands.

Done at Brussels, 14.4.2020

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