

Important information for downstream users of Chromium trioxide in the EEA supplied by Joint Stock Company Novotroitsk Plant of Chromium Compounds (NPCC)

REACHLaw as only representative applicant for **Joint Stock Company Novotroitsk Plant of Chromium Compounds (NPCC)** submitted an upstream application for authorisation for **four uses of chromium trioxide** by downstream users in its supply chain. The application was submitted before the latest application date and users in the NPCC supply chain have been covered by transitional arrangements since the sunset data for use of chromium trioxide in the EEA of **21.09.2017**.

The Commission adopted and published the decision for three of four uses on 14.12.2020.1

These uses covered by the decision are:

- Use 1: formulation
- Use 2: hard chrome plating
- Use 4: miscellaneous surface treatment

The review period granted for the three uses is **7 years** meaning that the authorisation will expire on **21.09.2024**.

AUTHORISATION CONDITIONS

The authorization decision impose a number of conditions on both REACHLaw as authorisation holder and NPCC downstream users that must be complied with by deadlines specified in the decision. The first of these is that REACHLaw must update the exposure scenarios and provide them in amended safety data sheets to NPCC downstream users by **14.03.2021** for them to apply the operational conditions and risk management measures at their sites without undue delay. NPCC downstream users must take into implementation annual monitoring programs for workers exposure and environmental emissions of Chromium (VI). They must have finished the first measurements by **14.06.2021**. Full details of all the conditions are given in the Commission decision given in the Annex.

REACHLAW HAS JOINED CTACSub

As of **01.01.2021**, REACHLaw as only representative for NPCC is now part of the CTACSub (CTAC Submission Consortium). CTACSub applicants received their authorisation decision on **18.12.2020** for five of the six uses they applied for. REACHLaw's application is identical in scope for four of the six CTACSub uses. The decision texts for the three common uses between the applications are identical. CTACSub have prepared a series of **Questions & answers for downstream users** on 22.12.2020.² NPCC downstream users are advised to follow the advice and instructions available from CTACSub relating to how to fulfil their obligations. Note that the dates given refer to the CTACSub decision and the deadlines for REACHLaw decision are 4 days earlier as the decision was issued 4 days earlier.

Business ID: 2052809-9
Municipality: Espoo, Finland

¹ Summary of the decision published in the Official Journal available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C .2020.442.01.0005.01.ENG&toc=OJ%3AC%3A2020%3A442%3ATOC

² Questions & answers published by the CTACSub consortium manager on December 22, 2020: Questions & Answers CTACSub1 (CTAC Submission Consortium)REACH Authorization of Certain Uses of Chromium Trioxide https://secureservercdn.net/160.153.137.14/8bm.f33.myftpupload.com/wp-content/uploads/CTACSub-Consortium-Questions-and-Answers-07-12-2020.pdf



JOIN A WEBINAR TO GET INFORMATION ON YOUR OBLIGATIONS

Ramboll as technical consultant for CTACSub have organized a webinar on the **15.01.2021** to brief downstream users on the authorisation decisions. All concerned downstream users are advised to join the webinar.

To sign up to this webinar, please click here

https://register.gotowebinar.com/register/5569451217499389963

DECORATIVE CHROME PLATING USE HAS NOT YET RECEIVED A DECISION

The remaining use (**Use 3: decorative chrome plating**) applied for has not yet received its decision as the Commission requested the submission of a substitution plan prior taking a decision. The substitution plan was submitted on 10.09.2020 based on input from users in the NPCC and CTACSub supply chains. More information on how the substitution plan will be assessed is available on the ECHA website.³ Until a decision is taken, use is permitted via transitional arrangements.

REACHLAW WILL SUBMIT A REVIEW REPORT

REACHLaw acting as only representative authorisation holder for NPCC will file a review report. More information will be available in the webinar of the 15.01.2021.

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Business ID: 2052809-9 Municipality: Espoo, Finland

³ Details of the assessment of authorisation substitution plans available on the ECHA website at https://echa.europa.eu/-/consultations-start-on-authorisation-substitution-plans

Annex: COMMISSION IMPLEMENTING DECISION of 14.12.2020 partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd)



Brussels, 14.12.2020 C(2020) 8735 final

COMMISSION IMPLEMENTING DECISION

of 14.12.2020

partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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COMMISSION IMPLEMENTING DECISION

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partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd)

(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 (EC) 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) Chromium trioxide 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.
- On 16 March 2016, REACHLaw Ltd, ('the applicant'), acting as only representative of Joint Stock Company Novotroitsk Plant of Chromium Compounds, submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for certain uses of chromium trioxide. The uses for which authorisation was sought are formulation of mixtures for functional chrome plating, functional chrome plating with decorative character and surface treatment (except passivation of tin-plated steel (electrolytic tin plating ETP)) for applications in various industry sectors, namely architectural, automotive, metal manufacturing and finishing and general engineering ('use 1'); functional chrome plating with decorative character ('use 3'); surface treatment (except ETP) for applications in various industry sectors, namely architectural, automotive, metal manufacturing and finishing, and general engineering ('use 4').
- (3) The overall assessment of use 3 by the Commission is ongoing and this should not delay the adoption of a decision concerning the other uses applied for. As a consequence, this Decision only covers uses 2, 4, and use 1, for the formulation of mixtures for uses 2 and 4.
- (4) On 30 May 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 Agency² ('the Agency') on the application sent to it pursuant to

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OJ L 396, 30.12.2006, p. 1.

https://echa.europa.eu/documents/10162/5dab062f-8e37-9dae-40bd-25fa2ca625be

the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006. RAC and SEAC confirmed that the application is an application made by a subsequent applicant in accordance with Article 63(1) of Regulation (EC) No 1907/2006. The applicant has demonstrated that it had permission from the previous applicants to refer to the relevant parts of the application for authorisation for certain uses of chromium trioxide made previously by Lanxess Deutchland GmbH and others. RAC and SEAC noted that the justifications for the opinions on that previous application are valid for the application made by REACHLaw Ltd with regard to the same uses.

- (5) In its opinions, RAC concluded that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of chromium trioxide in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. As a result, paragraph 2 of Article 60 of Regulation (EC) No 1907/2006 does not apply to that substance, and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.
- (6) In its opinions on uses 1, 2 and 4 for which the authorisation was sought, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risks to workers. In particular, 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 has 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, thereby preventing RAC from further evaluation. Those uncertainties concern the reliability and representativeness of the exposure data and its relation with the specific risk management measures in place. Nevertheless, the Commission considers that those uncertainties did not prevent SEAC from further analysing the application.
- (7) RAC further concluded that there are uncertainties in the assessment of exposure of the general population to chromium trioxide 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. Notwithstanding those uncertainties, RAC considered that the assessment of risks to the general population via the environment is 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.
- (8) Due to the uncertainties in the assessment of risks to workers and to the general population, RAC recommended additional conditions and monitoring arrangements as regards uses 1, 2 and 4. The Commission, having evaluated RAC's assessment, agrees with its conclusions and recommendations.

https://echa.europa.eu/documents/10162/c4fd2e61-4592-49e8-1e0b-34892be42ce7https://echa.europa.eu/documents/10162/d05d7ddc-67af-b7db-3c5c-e95b2d3f8165

- (9) In its opinions on uses uses 1, 2 and 4 of chromium trioxide described in the application, SEAC concluded that the overall socio-economic benefits outweigh the risk to human health arising from those uses. Concerning use 1, SEAC noted that the socio-economic benefits arising from that use, based on the expected social costs due to job losses alone, clearly outweigh the monetised human health impacts, which are calculated based on a worst case scenario. Other benefits, based on the avoided negative impacts due to disruptions in the supply chain, further strengthen that conclusion. Concerning uses 2 and 4, SEAC noted that the socio-economic benefits arising from those uses, based on the expected profit losses or on the social costs due to job losses alone, clearly outweigh the monetised human health impacts, which are calculated based on a worst case scenario. Other benefits, based on the avoided significant negative impacts due to disruptions in the supply chain for a number of affected industry sectors, further strengthen that conclusion. The Commission, having evaluated SEAC's assessment, agrees with those conclusions for uses 2, 4 and, as regards use 1, for the formulation of mixtures for uses 2 and 4.
- (10)An authorisation may be granted under Article 60(4) of Regulation (EC) No 1907/2006 if there are no suitable alternative substances or technologies. In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use applied for. Some potential alternatives may provide this functionality but at some loss to performance or in a manner that involves technical compromises. The Commission considers that, given the economic and other incentives towards substitution that already arise from inclusion in the authorisation system, and in the light of the objective of progressive substitution, as a starting point, the Commission should not consider a potential alternative to be technically viable where such losses to performance or technical compromises are not minor. Nevertheless, the Commission considers that it must be possible to depart from that 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 difference between the socioeconomic benefits and the risk to human health or the environment. The Commission considers that no particular factors justify less strict technical feasibility requirements in this case as regards uses 1, 2 and 4. 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.
- (11) In its opinion on use 1, considering that chromium trioxide has no 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. The Commission, having evaluated SEAC's assessment, agrees with that conclusion as regards the formulation of mixtures for uses 2 and 4.
- (12) In its opinions on uses 2 and 4, SEAC concluded that there are no suitable alternative substances or technologies. Due to the very broad scope of those uses, SEAC could not exclude possible uncertainty with regard to the technical feasibility of alternatives for a limited number of specific applications that are covered by the description of uses 2 and 4. As regards uses 2 and 4, the Commission agrees with SEAC's conclusion.
- (13) In order to ensure that the authorisation covers only those uses for which no suitable alternatives are available, the Commision considers it necessary to further specify the description of uses 2 and 4 by aligning it with the conclusions of the analysis of alternatives as presented in the application and as assessed by SEAC. As regards the

- absence of suitable alternatives for uses 2 and 4, the Commission considers that the applicant has only discharged its burden of proof in demonstrating the absence of suitable alternatives as regards uses 2 and 4 only with regard to such limited scope of the uses
- (14) Therefore, the description of uses 2 and 4 should be further specified by referring to uses where any of the following key functionalities is necessary for the use: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, effect on surface morphology, concerning use 2; corrosion resistance/active corrosion inhibition, layer thickness, humidity resistance, adhesion promotion (adhesion to subsequent coating or paint), resistivity, chemical resistance, wear resistance, electrical conductivity, compatibility with substrate, (thermo) optical properties (visual appearance), heat resistance, food safety, coating tension, electric insulation, deposition speed, concerning use 4.
- (15) In addition, the Commission took note of the complexity of the supply chains relevant for the uses applied for, the time and investment necessary to implement a potential alternative for specific niche applications, as well as the time necessary for its industrialisation and for the qualification of the resulting products in the supply chain. The Commission, having evaluated SEAC's assessment, and taking the above considerations into account, agrees with the conclusion that there are no suitable alternative substances or technologies with regard to uses 2 and 4 as limited in this Decision.
- (16) Concerning use 4, in order to ensure that the general public is not exposed to residual chromium (VI) in the concerned articles, it is appropriate to impose a condition excluding the presence of chromium (VI) in such articles.
- (17) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise uses 1, 2 and 4 as limited in this Decision, provided that the risk management measures and operational conditions described 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 uses 2 and 4 where the specified key functionalities are not necessary for the use.
- (18) 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.
- (19) Furthermore, in order to facilitate the enforcement of this Decision with regard to uses 2 and 4, it is 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 Article 1(1) which are required for their use, including a justification why such key functionalities are necessary for that use.
- (20) In its opinions, SEAC recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 be set at seven years for uses 1 and 2 and at four years for use 4. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and in particular, concerning use 1, the concerns related to the appropriateness and effectiveness of the

risk management measures and operational conditions, the additional conditions and monitoring arrangements to address those concerns, the conclusion that chromium trioxide has no independent function at the stage of formulation and, consequently, that any substitution for use 1 is linked to the substitution of the subsequent uses of the formulated mixtures, the expected social costs due to unemployment and the expected negative economic consequences in the supply chain in case no authorisation is granted. Concerning uses 2 and 4, the Commission takes into account in particular the concerns related to the appropriateness and effectiveness of the risk management measures and operational conditions, the additional conditions and monitoring arrangements imposed by this Decision to address those concerns, the time necessary to implement and industrialise possible alternatives should they become available, the uncertainties arising from the broad scope of the uses applied for, the expected social costs due to unemployment and the expected significant negative economic consequences in the supply chain in case no authorisation is granted.

- (21) For uses 1 and 2 it is appropriate to set the review period at seven years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- Considering that the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 must be submitted at least 18 months before the expiry of the review period, and in view of the conditions and the time-limits for compliance with such conditions established by this Decision, the review period recommended by SEAC for use 4 would make it practically impossible for the authorisation holder to submit a review report within the time-limit in the present case. Therefore, for that use it is appropriate to set the review period at four years from the date of adoption of this Decision, in order to provide the authorisation holder an adequate period of time to prepare a review report. Nevertheless, taking into account the delay in adopting this Decision, it is also appropriate to align the expiration date of the review period of use 4 to the one set out for uses 1 and 2.
- (23) The language used to describe 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 a use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of that Member State.
- This Decision does not affect the obligation of the authorisation holder to ensure that the use of a substance does not adversely affect human health or the environment having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible or the obligation of the employer under Articles 4(1) and 5 of Directive 2004/37/EC of the European Parliament and of the Council³ to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or

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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).

- safety. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/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.
- (25) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council⁸ or Directive 2010/75/EU of the European Parliament and of the Council nor any obligation to comply⁹ 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 the environmental quality standards 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 emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.
- (26) The measures provided for in this Decision are in accordance with the opinion of the committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

1. An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation numbe	Authorised use			
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REACH/20/17/0 Formulation of mixtures exclusively for uses REACH/20/17/1 and REACH/20/17/2

REACH/20/17/1 Functional chrome plating where any of the following key

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).

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).

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).

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).

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).

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).

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).

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).

functionalities is necessary for the intended use: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, or effect on surface morphology

REACH/20/17/2

Surface treatment (except passivation of tin-plated steel (ETP)) for applications in various industry sectors (unrelated to functional chrome plating or functional chrome plating with decorative character) namely architectural, automotive, metal manufacturing and finishing, and general engineering, where any of the following key functionalities is necessary for the intended use: corrosion resistance/ active corrosion inhibition, layer thickness, humidity resistance, adhesion promotion (adhesion to subsequent coating or paint), resistivity, chemical resistance. wear resistance. electrical conductivity. compatibility with substrate, (thermo) optical properties (visual appearance), heat resistance, food safety, coating tension, electric insulation, or deposition speed

- 2. An authorisation for the use of chromium trioxide is not granted for functional chrome plating where none of the key functionalities listed in paragraph 1 regarding that use is necessary for the use.
- 3. An authorisation for the use of chromium trioxide is not granted for surface treatment for applications in various industry sectors where none of the key functionalities listed in paragraph 1 regarding that use is necessary for the use.
- 4. The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety reports ¹² as well as to the conditions laid down in this Decision.

Article 2

- 1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 9.
- 2. The authorisation holder shall develop specific exposure scenarios for representative processes, operations and individual tasks (including automatic versus manual systems and open versus closed systems and combinations thereof), describing risk management measures and operational conditions representative of all sites where the authorised uses take place, 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 holder shall select the risk management measures described in 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

https://ec.europa.eu/docsroom/documents/23664 https://ec.europa.eu/docsroom/documents/23665 https://ec.europa.eu/docsroom/documents/23667

- available to the competent authorities of the Member State where an authorised use takes place.
- 3. The specific exposure scenarios shall be made available to the downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 ('downstream users'), in an updated safety data sheet, by 14 March 2021. The authorisation holder and the downstream users shall apply the risk management measures and operational conditions included in the specific exposure scenarios without undue delay.
- 4. The authorisation holder shall verify and validate the specific exposure scenarios referred to in paragraph 2 by 14 June 2022 by making an analysis of tasks, using exposure and emission data measured by downstream users and related contextual information and by means of monitoring programmes of occupational exposure and environmental releases measurements referred to in paragraph 6, as regards all the processes described for the authorised uses. The validated and verified exposure scenarios shall be immediately made available to the downstream users.
- 5. The information to be made available to downstream users referred to in paragraph 3 and 4 shall also include detailed guidance on how to select and apply risk management measures. That information shall be submitted, upon request, by the authorisation holder and the downstream users to the competent authorities of the Member States where the authorised uses take place.
- 6. The authorisation holder and the downstream users shall implement the following monitoring programmes for chromium (VI):
 - (a) At least annual air monitoring programmes on occupational exposure to chromium (VI) in accordance with Article 5(5)(e) of Regulation 2004/37/EC. The first measurements shall be performed without delay and at the latest on 14 June 2021. Those programmes shall be based on relevant standard methodologies or protocols and be representative of:
 - (i) the range of tasks undertaken where exposure to chromium is possible, including tasks involving process and maintenance workers;
 - (ii) the operational conditions and risk management measures typical for each of these tasks;
 - (iii) the number of workers potentially exposed;
 - (b) at least annual monitoring programmes for chromium (VI) emissions to wastewater and air from local exhaust ventilation. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the operational conditions and risk management measures (such as waste water treatment systems, gaseous emission abatement techniques) used at the individual sites where relevant measurements are carried out.
- 7. The authorisation holder and the downstream users shall use the information gathered via the measurements referred to in paragraph 6 and related contextual information to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions in place and to introduce measures to further reduce exposure and emissions. The results of those measurements as well as of any action taken following the review shall be documented and made available

- by the authorisation holder and the downstream users, upon request, to the competent authorities of the Member State where the authorised uses take place.
- 8. The authorisation holder shall draw up recommendations and guidelines to assist downstream users in carrying out the monitoring programmes referred to in paragraph 6 and shall develop a report template for submission of monitoring data by downstream users according to paragraph 9. The report template shall be supplied to the downstream users together with the updated safety data sheet referred to in paragraph 3.
- 9. The downstream users shall make available to the Agency the information collected from the monitoring programmes in accordance with paragraph 6, including the contextual information related to each set of measurements, in the format of the template referred to in paragraph 8, for the first time by 14 December 2021, for transmission to the authorisation holder for the purpose of verifying and validating the specific exposure scenarios referred to in paragraph 2 and for the preparation of the review report.

Article 3

The authorisation bearing number REACH/20/17/2 shall be subject to the following specific conditions:

- (a) as regards spraying operations, the downstream users shall apply the risk management measures and operational conditions set out in the Annex;
- (b) the area in which spraying operations take place shall be restricted either physically by means of barriers and signalling or through the implementation of strict procedures during the activity, which shall continue being applied for a specified time after the spray application has ceased;
- (c) workers shall not remove the respiratory protective equipment used in spraying operations until they have left the area of application.

Article 4

The authorisation bearing number REACH/20/17/2 shall be subject to the condition that the authorisation holder and its downstream users ensure that there is no chromium (VI) above the detectable level present in articles for supply to the general public.

Article 5

As regards the authorisation bearing numbers REACH/20/17/1 and REACH/20/17/2, the downstream users shall include in the notification to the Agency pursuant to Article 66(1) of Regulation (EC) No 1907/2006 an explanation of the key functionalities of chromium trioxide listed in Article 1(1) which are necessary for their use, including a justification why such key functionalities are necessary for that use.

Article 6

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2024.

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 7

In the event that the authorisation holder submits a review report, it shall include the following information:

- (a) the information related to the specific exposure scenarios referred to in Article 2(2), the verified and validated exposure scenarios referred to in Article 2(4), detailed guidance on how to select and apply risk management measures as referred to in Article 2(5), the information gathered via the measurements referred to in Article 2(6) and related contextual information and the documents on the action taken following each review referred to in Article 2(7);
- (b) a refined assessment of the exposure to chromium (VI) of the general population 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 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 the general population via the environment, including the oral route, shall be included in the assessment.

Article 8

Upon request, the authorisation holder shall submit a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised uses take place in an official language of that Member State.

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

Article 9

This Decision is addressed to REACHLaw Ltd, Vänrikinkuja 3 JK 21, 02600, Espoo, Finland. Done at Brussels, 14.12.2020

For the Commission Thierry BRETON Member of the Commission

> CERTIFIED COPY For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION



Brussels, 14.12.2020 C(2020) 8735 final

ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING DECISION of XXX

partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACHLaw Ltd)

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ANNEX

Risk management measures and operational conditions referred to in Article 3(a) for spraying operations in working contributing scenarios numbers 2, 4, 6, 16, 24, 25 and 26 in the chemical safety report referred to in Article 1(4) of the authorisation bearing number REACH/20/17/2.

Contributing scenario	Duration and frequency of exposure	Concentration of the substance	Local exhaust ventilation (LEV) used	Respiratory protective equipment (RPE) used and its effectiveness	Other risk management measures
WCS 2 (PROC 8b) Decanting – liquids	< 30 min (combined for WCS 2, 4 and 6)	Cr(VI) in mixture: substantial (10-50%)	Yes	yes, full-face- mask with A2P3 filter, effectiveness 99.75%	good natural ventilation and medium level of containment
WCS 4 (PROC 5) Mixing-liquids		Cr(VI) in mixture: substantial (10-50%)			good natural ventilation and low level of containment
WCS 6 (PROC 8b) Re-filling of baths – liquids		Cr(VI) in mixture: substantial (10-50%)			good natural ventilation
WCS 16 (PROC 7) Surface treatment by spraying in spray cabin/spray booth	< 30 min	Cr(VI) in mixture: small (1-5%)	yes, fixed capturing hood (90% reduction)	yes, full-face- mask with A2P3 filter, effectiveness 99.75%	down-flow spray-room (80% reduction)
WCS 24 (PROC 8b) Cleaning of equipment – tools cleaning (closed system)	< 15 min	Cr (VI) in mixture: minor (5-10%)	yes, fixed capturing hood (90% reduction)	yes, full-face- mask with A2P3 filter, effectiveness 99.75%	good natural ventilation, closed system

WCS 25 (PROC 8b) Cleaning and maintenance of equipment — tools cleaning (spray cabin)	< 15 min	Cr (VI) in mixture: minor (5-10%)	No	specialized ventilation: more than 10 ACH, indoor in spray room
WCS 26 (PROC 8b) Cleaning – Spray cabin and ancillary areas	< 15 min	Cr (VI) in mixture: minor (5-10%)	No	good natural ventilation