# PRESS RELEASE<sup>1</sup> FEBRUARY 21, 2019

The <u>CTACSub Consortium</u> (CTAC Submission Consortium)<sup>2</sup> is pleased to confirm that after a delay of more than two years, the European Commission will finally authorize the applied for six essential uses of chromium trioxide (EC 215-607-8; CAS 1333-82-0), after a qualified majority vote (24 in favor, 4 against) in the REACH Committee on February 15, 2019.

The review periods granted are 7 years from the Sunset Date for Use 1 (formulation), Use 2 (hard chrome plating), and Use 4 (surface treatment aeronautics and space); and 4 years from the date of the authorization decision for Use 3 (functional chrome with decorative character), Use 5 (miscellaneous surface treatment) and Use 6 (passivation of tin-plated steel (ETP)).

The authorization decisions contain a number of conditions, which will be challenging to comply with, including on timing. The time lines are set out below.

Date	Action		
April 1, 2019	Authorization decision notified to applicants (date estimated)		
July 1, 2019	Authorization holders to draw up and distribute (as annexes to safety data sheets) specific exposure scenarios for representative processes, operations and individual tasks		
July 1, 2019	Downstream users to notify uses to ECHA under Art. 66 REACH		
October 1, 2019	Downstream users to finish first exposure measurement campaigns		
April 1, 2020	Downstream users to notify data from exposure measurements and air and waste water monitoring to ECHA		
October 1, 2020	Authorization holders to validate exposure scenarios with new data from exposure measurements and air / wastewater monitoring which they will have received from Downstream users via ECHA		
October 1, 2021	Authorization holders to file review report for Uses 3, 5, and 6 if they decide to continue upstream application		
April 1, 2023	End of review period for Uses 3, 5 and 6		
March 21, 2023	Authorization holders to file review report for Uses 1, 2 and 4 if they decide to continue upstream application		
September 21, 2024	End of review period for Uses 1, 2, 4		

Dr. Martin Kleban, Chair of CTACSub explains: "The authorization holders will now actively work together with Downstream users to implement the authorization decisions. The success of implementation will heavily depend on whether the Downstream users will all provide to ECHA complete and accurate measurement and monitoring data. Downstream user compliance will also play a major role in the decision how the authorization holders will approach the review reports, i.e. whether they will continue with upstream application or not."

The CTACSub Consortium has made available Good Practice Sheets and Q&As to help with implementation, see at <a href="https://www.jonesdayreach.com">www.jonesdayreach.com</a>.

Attachment: Text adopted at REACH Committee February 15, 2019

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Atotech Deutschland GmbH; Aviall Services Inc; CROMITAL S.P.A in its legal capacity as Only Representative of Soda Sanayii A.S.; Elementis Chromium LLP in its legal capacity as Only Representative of Elementis Chromium Inc.; LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd.; MacDermidEnthone GmbH; Prospere Logistic Baltic OÜ in its legal capacity as Only Representative of Aktyubinsk Chromium Chemicals Plant, Kazakhstan.



Brussels, XXX [...](2019) XXX draft

## **COMMISSION IMPLEMENTING DECISION**

of XXX

granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others)

(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<sup>1</sup>, and in particular Article 64(8) thereof,

#### Whereas:

- (1) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.
- (2) On 11 May 2015, LANXESS Deutschland GmbH (acting as only representative of the LANXESS CISA (Pty) Ltd), Atotech Deutschland GmbH, Aviall Services Inc, Enthone GmbH<sup>2</sup>, BONDEX TRADING LTD (acting as only representative of Aktyubinsk Chromium Chemicals Plant), CROMITAL S.P.A. (acting as only representative of Soda Sanayii A.S.) and Elementis Chromium LLP (acting as only representative of Elementis Chromium Inc) ('the applicants') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the uses of chromium trioxide in the formulation of mixtures ('use 1'); in functional chrome plating ('use 2'); in functional chrome plating with decorative character ('use 3'); in surface treatment for applications in the aeronautics and aerospace industries (unrelated to functional chrome plating or functional chrome plating with decorative character) ('use 4'); in 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 (unrelated to functional chrome plating or functional chrome plating with decorative character) ('use 5'); and in passivation of tin-plated steel (ETP) ('use 6').

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OJ L 396, 30.12.2006, p. 1.

Enthone GmbH subsequently changed its name to MacDermid Enthone GmbH.

- (3) On 21 March 2018 a legal entity change was notified to the European Chemicals Agency (the 'Agency') pursuant to which the application was transferred from the original applicant BONDEX TRADING LTD to Prospere Logistic Baltic OÜ.
- (4) On 30 September 2016, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the Agency<sup>3</sup> on the application, pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (5) In its opinions, RAC confirmed 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 therefore that chromium trioxide is a non-threshold substance for the purposes of Article 60(3)(a) of that Regulation. In accordance with that Article, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.
- (6) In its opinions on uses 1 to 5, 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.
- (7) Concerning uses 1 to 5, 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 how it relates to the specific risk management measures in place, particularly for use 4 where, in addition to bath immersion, different activities including spraying, rolling, brushing and machining operations are covered by the application and the applicant has not been able to fully assess the combined exposure related to all those tasks. Nevertheless the Commission considers that those uncertainties did not prevent SEAC from further analysing the application.
- (8) Concerning uses 1 to 5, 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 man via the environment provided to be sufficient for further analysis by SEAC, noting that the approach by the applicants 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 occurs rapidly under most environmental conditions.

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- (9) In its opinions on uses 1 to 5, due to the uncertainties in the assessment of risks to workers and to man via the environment, RAC recommended additional conditions and monitoring arrangements for the authorisation. The Commission, having evaluated RAC's assessment, concurs with that conclusion.
- (10)In its opinion on use 6, RAC concluded that the risk management measures and operational conditions as described in the application, and as further detailed by the applicants at the request of RAC, are appropriate and effective in limiting the risks to workers and the general population that could potentially be exposed via the environment. However, RAC concluded that there is a lack of specific data for the nine sites concerned and that uncertainties 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 and related oral exposure via drinking water. Nonetheless, RAC considered the assessment to be sufficient for further analysis by SEAC, noting that the approach by the applicants was based on assumptions that were 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 occurs rapidly under most environmental conditions. RAC further acknowledged that the description of contributing scenarios and the exposure assessment in the application would have benefitted from an assessment more specific to use 6 and that there are some uncertainties related to the frequency and combination of tasks performed by individual workers but considered the impact of those uncertainties on total exposure to
- (11) In its opinion on use 6, due to the uncertainties in the combination and frequency of tasks performed by individual workers, in order to address the variability of the operational conditions and risk management measures implemented among different sites and due to the limited representativeness of the data supporting the assessment of the exposure of man via the environment, RAC recommended additional conditions and monitoring arrangements for the authorisation. The Commission, having evaluated the RAC's assessment, concurs with that conclusion.
- (12) In its opinions as regards all six uses of chromium trioxide applied for, SEAC concluded that the overall socio-economic benefits arising from each of those uses outweigh the risk to human health arising from those uses. Concerning use 1, SEAC noted that the socio-economic benefits arising from the use of the substance, 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, 3, 4, 5 and 6, SEAC noted that the socio-economic benefits arising from the use of the substance, 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 this conclusion. The Commission, having evaluated SEAC's assessment, concurs with those conclusions.
- (13) 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, concurs with that conclusion.
- (14) In its opinions on uses 2, 3, 4 and 5, SEAC concluded that there are no suitable alternative substances or technologies. Due to the very broad scope of the intended 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 the uses applied for.
- (15) In order to ensure that the authorisation covers only those uses for which no suitable alternatives are available, the Commision considers necessary to further specify the description of the uses by aligning it with the conclusions of the analysis of alternatives as presented in the application and as assessed by SEAC.
- Therefore, the description of the authorised uses should be further specified by referring (16)it to uses where any of the following key functionalities or properties, or a combination thereof is necessary for the intended use: wear resistance, hardness, layer thickness, corrosion resistance, coefficient of friction, and effect on surface morphology concerning use 2; corrosion resistance, chemical resistance, wear/abrasion resistance, prevention of nickel leaching, adhesion, hardness, sunlight/UV resistance, temperature/heat resistance, electrical conductivity, reflection behaviour/absorption capability, and aesthetics concerning use 3; corrosion resistance/active corrosion inhibition, chemical resistance, hardness, adhesion promotion (adhesion to subsequent coating or paint), temperature resistance, resistance to embrittlement, wear resistance, surface properties impeding deposition of organisms, layer thickness, flexibility, and resistivity concerning use 4; 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, and deposition speed concerning use 5.
- (17) Concerning use 4, the application referred to the 'inhibition of biological organisms, biostatic properties' as key functionalities or properties, or a combination thereof, for achievement of which the use of chromium trioxide is necessary. Such a reference in the description of use may create confusion with the use of chromium trioxide as a biocidal product as defined in Article 3(1)(a) of Regulation (EU) No 528/2012 of the European Parliament and of the Council<sup>4</sup>. Under that Regulation chromium trioxide cannot be placed on the market, nor used as a biocidal product, and this Decision cannot authorise such use, in accordance with Article 56(4)(b) of Regulation (EC) No 1907/2006. Therefore, to avoid confusion, the term 'inhibition of biological organisms, biostatic properties' should be replaced by 'surface properties impeding deposition of organisms' in the description of use 4 as authorised by this Decision, as chromium trioxide is in fact used for achieving or enabling that latter function or properties.
- (18) In addition, the Commission took note of the complexity of the supply chains concerned by the uses applied for, the time and investment necessary to implement a potential alternative, as well as the time necessary for its industrialisation and for the qualification of the resulting products in the supply chains. The Commission, having evaluated

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

- SEAC's assessment, and taking the above considerations into account, concurs with the conclusion that there are no suitable alternative substances or technologies for uses 2, 3, 4 and 5.
- (19) In its opinion on use 6, SEAC concluded that there are no suitable alternative substances or technologies. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.
- (20) Concerning use 5, in order to ensure that the general public is not exposed to residual chromium VI in articles, it is appropriate to impose a condition excluding the presence of chromium (VI) in such articles.
- (21) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the six uses of chromium trioxide applied for, as specified by this Decision, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report<sup>5</sup>, as well as the conditions set out in this Decision, are fully applied.
- (22)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, 2 and 4 and at four years for uses 3, 5 and 6. The Commission takes 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 recommended additional conditions and monitoring arrangements to address those concerns, the fact that chromium trioxide has no independent function at the stage of formulation and, consequently, that any substitution for use 1 is interlinked with 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 of no authorisation. Concerning uses 2, 3, 4, and 5, the Commission takes into account in particular the concerns related to the appropriateness and effectiveness of the the risk management measures and operational conditions, the strict 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 applicant's approach mainly due to 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 of no authorisation. Concerning use 6, the Commission takes into account in particular the concerns related to the appropriateness and effectiveness of the the risk management measures and operational conditions in limiting the risk, the time necessary to implement and industrialise a promising alternative should one become available, the uncertainties arising from the applicants' approach mainly due to the broad scope, the expected social costs due to unemployment and the expected significant negative economic consequences in the

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- supply chain in case of no authorisation. Based on the above, the Commission concurs with SEAC's recommendations concerning the review periods for the six uses.
- (23) 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 of the authorisation and the timelines thereof, the review period recommended by the SEAC for uses 3, 5 and 6 would make it practically impossible for the authorisation holders to submit a review report in the present case. Therefore, for those uses, it is appropriate to provide for the review period of four years from the date of adoption of this Decision, in order to provide the authorisation holders an adequate period of time to prepare a review report.
- (24) Furthermore, it is appropriate that the review period be set at seven years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006 as regards uses 1, 2 and 4.
- (25) In its opinions for uses 2, 3, 4 and 5, due to the broad scope of these uses, SEAC recommended that in the event that the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 is submitted, the authorisation holder should refine the description of the authorised uses or provide more detailed assessment of the uses applied for. The Commission concurs with that recommendation.
- (26) 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 languages of the Member States where the uses take place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require the authorisation holders to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member States concerned.
- 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 pursuant to 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<sup>6</sup>, or to prevent and reduce exposure in accordance with Article 5 of that Directive. Furthermore, this Decision is without prejudice to the application of Union law in the area of health and safety at work, in

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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).

- particular Council Directives 89/391/EEC<sup>7</sup>, 92/85/EEC<sup>8</sup>, 94/33/EC<sup>9</sup> and 98/24/EC<sup>10</sup> and Directive 2004/37/EC as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.
- This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC<sup>11</sup> and 2010/75/EU<sup>12</sup> of the European Parliament and of the Council, as well as with emission limit values set to achieve compliance with the environmental quality standards established both by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council<sup>13</sup> and in Directive 2008/105/EC of the European Parliament and of the Council<sup>14</sup>. Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.
- (29) Since the United Kingdom notified on 29 March 2017 its intention to leave the Union, pursuant to Article 50 of the Treaty on European Union, the Treaties will cease to apply to the United Kingdom from the date of entry into force of the withdrawal agreement or, failing that, two years after the notification, unless the European Council, in agreement with the United Kingdom, decides to extend that period. As a consequence, and without prejudice to any provisions of the withdrawal agreement, this Commission Decision, as far as it addresses a legal entity established in the United Kingdom, only applies until the United Kingdom ceases to be a Member State.
- (30) 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 chromium trioxide (EC No 215-607-8; CAS No 1333-82-0), provided

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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).

that the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation, and once available, according to the conditions described in the specific exposure scenarios to be developed pursuant to Article 2(2) of this Decision, as well as the conditions laid down in Articles 2, 3 and 4 of this Decision are fully applied:

Authorisation number	Authorisation holder	Authorised use
REACH/19/16/0	LANXESS Deutschland GmbH	Formulation of mixtures
REACH/19/16/1	Atotech Deutschland GmbH	
REACH/19/16/2	Aviall Services Inc	
REACH/19/16/3	Prospere Logistic Baltic OÜ	
REACH/19/16/4	CROMITAL S.P.A.	
REACH/19/16/5	Elementis Chromium LLP	
REACH/19/16/6	MacDermid Enthone GmbH	
REACH/19/16/7	LANXESS Deutschland GmbH	Functional chrome plating where any of the following key functionalities
REACH/19/16/8	Atotech Deutschland GmbH	or properties, or a combination thereof, is necessary for the intended
REACH/19/16/9	Aviall Services Inc	use: wear resistance, hardness, layer thickness, corrosion resistance,
REACH/19/16/10	Prospere Logistic Baltic OÜ	coefficient of friction, and effect on
REACH/19/16/11	CROMITAL S.P.A.	surface morphology
REACH/19/16/12	Elementis Chromium LLP	
REACH/19/16/13	MacDermid Enthone GmbH	
REACH/19/16/14	LANXESS Deutschland GmbH	Functional chrome plating with decorative character (where any of
REACH/19/16/15	Atotech Deutschland GmbH	the following key functionalities or properties, or a combination thereof,
REACH/19/16/16	Aviall Services Inc	is necessary for the intended use: corrosion resistance, chemical
REACH/19/16/17	Prospere Logistic Baltic OÜ	resistance, wear/abrasion resistance, prevention of nickel leaching,
REACH/19/16/18	CROMITAL S.P.A.	adhesion, hardness, sunlight/ UV
REACH/19/16/19	Elementis Chromium LLP	resistance, temperature/ heat resistance, electrical conductivity,
REACH/19/16/20	MacDermid Enthone GmbH	

		reflection behaviour/ absorption capability, and aesthetics)
REACH/19/16/21	LANXESS Deutschland GmbH	Surface treatment for applications in the aeronautics and aerospace
REACH/19/16/22	Atotech Deutschland GmbH	industries, unrelated to functional chrome plating or functional chrome
REACH/19/16/23	Aviall Services Inc	plating with decorative character (where any of the following key
REACH/19/16/24	Prospere Logistic Baltic OÜ	functionalities or properties, or a combination thereof, is necessary for
REACH/19/16/25	CROMITAL S.P.A.	the intended use: corrosion resistance
REACH/19/16/26	Elementis Chromium LLP	/ active corrosion inhibition, chemical resistance, hardness,
REACH/19/16/27	MacDermid Enthone GmbH	adhesion promotion (adhesion to subsequent coating or paint), temperature resistance, resistance to embrittlement, wear resistance, surface properties impeding deposition of organisms, layer thickness, flexibility, and resistivity)
REACH/19/16/28	LANXESS Deutschland GmbH	Surface treatment (except passivation
REACH/19/16/29	Atotech Deutschland GmbH	of tin-plated steel (electrolytic tin plating - ETP)) for applications in architectural, automotive, metal
REACH/19/16/30	Aviall Services Inc	manufacturing and finishing, and general engineering industry sectors
REACH/19/16/31	Prospere Logistic Baltic OÜ	(unrelated to functional chrome
REACH/19/16/32	CROMITAL S.P.A.	plating or functional chrome plating with decorative character) (where
REACH/19/16/33	Elementis Chromium LLP	any of the following key functionalities or properties, or a
REACH/19/16/34	MacDermid Enthone GmbH	combination thereof, 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, and deposition speed)

REACH/19/16/35 LANXESS Deutschland GmbH

REACH/19/16/36 Atotech Deutschland GmbH Passivation of tin-plated steel (electrolytic tin plating - ETP)

REACH/19/16/37 Aviall Services Inc

REACH/19/16/38 Prospere Logistic Baltic OÜ

REACH/19/16/39 CROMITAL S.P.A.

REACH/19/16/40 Elementis Chromium LLP

REACH/19/16/41 MacDermid Enthone GmbH

#### Article 2

- 1. The conditions set out in paragraphs 2 to 8 shall apply to the authorisations bearing numbers REACH/19/16/0 to REACH/19/16/34.
- The authorisation holders shall develop specific exposure scenarios for representative 2. 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 representative for all sites at which the authorised uses take place, 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 upon request. 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, at the latest on ... [insert date – three months from date of adoption of this Decision].
- 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 ... [18 months from the date of adoption of this Decision] by making an analysis of tasks, using exposure and emission data measured by downstream users and related contextual information and by means of representative programmes of occupational exposure and environmental releases measurements, relating to all processes described for the authorised uses.
- 4. The information to be made available to downstream users referred to in paragraph 2 shall also include detailed guidance on how to select and apply risk management measures. That information shall be submitted, upon request, to the competent authorities of the Member States where the authorised uses take place.
- 5. The authorisation holders and their downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall implement the following monitoring programmes for chromium (VI):

- (a) annual 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 ... [six months from the date of adoption of this Decision]. Those programmes shall be based on relevant standard methodologies or protocols and be representative of:
  - (1) the range of tasks undertaken where exposure to chromium is possible, including tasks involving process and maintenance workers;
  - (2) the operational conditions and risk management measures typical for each of those tasks:
  - (3) the number of workers potentially exposed;
- (b) monitoring programmes for chromium (VI) emissions to wastewater and air from local exhaust ventilation. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the operational conditions and risk management measures (such as waste water treatment systems, gaseous emission abatement techniques) used at the individual sites where measurements are carried out.
- 6. The information gathered via the measurements referred to in paragraph 5 and related contextual information shall be used by the authorisation holders and by their downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006, 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.
- 7. The authorisation holders' downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall make available to the Agency the information from the monitoring programmes referred to in paragraph 5, including the contextual information related to each set of measurements, for the first time by ... [12 months from the date of adoption of this Decision], for transmission to the authorisation holder for the purpose of validating the exposure scenarios referred to in paragraph 2 and afterwards for the preparation of the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006. That information shall also be maintained and be made available by the authorisation holders and downstream users, upon request, to the competent authorities of the Member States where an authorised use takes place.
- 8. Following implementation by the authorisation holders' downstream users to whom this Decision applies of the revised risk management measures and operational conditions made available as part of the specific exposure scenarios in accordance with paragraph 2, those downstream users may reduce the frequency of measurements, once they can clearly demonstrate to the competent authority of the Member State where the use takes place that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions correspond to the exposure scenarios developed in accordance with paragraph 2 and function appropriately.

## Article 3

The authorisation for uses bearing authorisation numbers REACH/19/16/21 to REACH/19/16/34 shall be subject to the following condition: as regards spraying operations, the authorisation holders' downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall apply the risk management measures and operational conditions set out in the Annex. 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. Workers shall not remove the respiratory protective equipment (RPE) used in spraying operations until they have left the area of application.

#### Article 4

The authorisation bearing numbers REACH/19/16/28 to REACH/19/16/34 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

- 1. The conditions set out in paragraphs 2 to 4 shall apply to the authorisations bearing numbers REACH/19/16/35 to REACH/16/19/41.
- 2. The authorisation holders' downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall implement best practices to reduce workplace exposure to chromium trioxide and emissions to the environment to as low a level as technically and practically feasible, including the use of closed systems and automation, whenever possible. Where this is not possible, authorisation holders' downstream users to whom this Decision applies shall use local exhaust ventilation (LEV) systems that are appropriately designed, dimensioned, located and maintained to capture and remove chromium trioxide. Where closed systems and automation are not used, the non-use of LEV can only be justified in exceptional circumstances in case the use of LEV is technically impossible. The authorisation holders' downstream users to whom this Decision applies shall make the information on LEV systems put in place in the installations where the authorised uses are taking place, as well as of their maintenance available for inspection by the competent authorities.
- 3. Where RPE is needed to control exposure to chromium trioxide, it shall be used in accordance with standard procedures for use and maintenance and shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, ensuring training and medical fitness checking of the wearer, as well as supervision and maintenance of the RPE.
- 4. The authorisation holders' downstream users shall select the risk management measures described in the exposure scenarios in accordance with Article 5 of Directive 2004/37/EC. The selection shall be duly documented and justified and made available to the competent authorities upon request.

## Article 6

1. As regards the uses bearing authorisation numbers REACH/19/16/0 to REACH/19/16/13 and REACH/19/16/21 to REACH/19/16/27, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2024.

The authorisations referred to in the first subparagraph shall cease to be valid on 21 September 2024 with regard to the authorisation holders who have not submitted the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 by 21 March 2023, unless a decision to withdraw the authorisation is adopted earlier.

2. As regards the uses bearing authorisation numbers REACH/19/16/14 to REACH/19/16/20 and REACH/19/16/28 to REACH/18/16/41, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on ... [four years from the date of adoption this Decision].

The authorisations referred to in the first subparagraph shall cease to be valid on ... [four years from the date of this Decision] with regard to the authorisation holders who have not submitted the review report referred to in Article 61(1) of Regulation EC No 1907/2006 by... [30 months from the date of adoption this Decision], unless a decision to withdraw the authorisation is adopted earlier.

## Article 7

- 1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply to the authorisations bearing numbers REACH/19/16/35 to REACH/19/16/41.
- 2. The authorisation holders, as well as their downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006, shall implement at least annual air monitoring programmes for 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 ... [six months from the date of adoption of this Decision]. 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 those tasks;
  - (iii) the number of workers potentially exposed.
- 3. The authorisation holders and their downstream users shall implement monitoring programmes for chromium (VI) emissions to wastewater and air from local exhaust ventilation. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the operational conditions and risk management measures (such as waste water treatment systems, gaseous emission abatement techniques) used at the individual sites where measurements are carried out.
- 4. The information gathered via the measurements referred to in paragraph 2 and related contextual information shall be used by the authorisation holders and by their

- downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006, 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.
- 5. The authorisation holders' downstream users, to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006, shall make available to the Agency the information from the monitoring programmes referred to in paragraph 2, including the contextual information associated to each set of measurements, for the first time by ...[12 months from the date of adoption of this Decision], for transmission to the authorisation holder for the preparation of the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006. That information shall also be maintained and be made available by the authorisation holders and downstream users, upon request, to the competent authorities of the Member States where an authorised use takes place.

#### Article 8

In the event that a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006 is submitted, 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(5) and (6);
- (b) the information referred to in Article 6(2);
- (c) a refined assessment of the exposure to chromium (VI) of humans via the environment, as well as of the resulting risks. This 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 15 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 9

On request of the competent authority of the Member State where the authorised uses take place, the authorisation holders shall submit to that authority 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 10

This Decision is addressed to:

- (2) (1) LANXESS Deutschland GmbH, Kennedyplatz 1, 50569 Köln, NRW Germany;
- (2) Atotech Deutschland GmbH, Erasmusstraße 20, 10553, Berlin, Germany;

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

- (3) Aviall Services Inc, Schillingweg 40, 2153PL, Nieuw-Vennep, Noord-Holland, Netherlands;
- (4) Prospere Logistic Baltic OÜ, Harju maakond, Kesklinna linnaosa, Parnu mnt 110-7 Tallinn, 11313 Estonia;
- (5) CROMITAL S.P.A., Strada Quattro, Pal. A7, 20090, Assago (MI), Italia;
- (6) Elementis Chromium LLP, Elementis ChromiumEaglescliffe, TS16 0QG, Stockton on Tees, United Kingdom;
- (7) MacDermid Enthone GmbH, Elisabeth-Selbert-Str. 4, 40764, Langenfeld, Germany.

Done at Brussels,

For the Commission Elżbieta BIEŃKOWSKA Member of the Commission



Brussels, XXX [...](2019) XXX draft

ANNEX 1

## **ANNEX**

to the

# COMMISSION IMPLEMENTING DECISION of XXX

granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Lanxess Deutschland GmbH and others)

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# **ANNEX**

1. Risk management measures and operational conditions referred to in Article 3 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 of uses bearing authorisation numbers REACH/19/16/21 to REACH/19/16/27

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  WCS 4 (PROC 5)  Mixing- liquids  WCS 6 (PROC 8b)  Re-filling of baths – liquids	< 30 min (combined for WCS 2, 4 and 6)	Cr(VI) in mixture: substantial (10-50%)  Cr(VI) in mixture: substantial (10-50%)  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  good natural ventilation and low level of containment  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) and fixed capturing hood (90% 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

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 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

2. Risk management measures and operational conditions referred to in Article 3 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 of uses bearing authorisation numbers REACH/19/16/28 to REACH/19/16/34

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		Cr(VI) in mixture:			good natural ventilation

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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
baths – liquids		substantial (10-50%)			
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

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