#### December 22, 2020

#### **Questions & Answers**

## CTACSub<sup>1</sup> (CTAC Submission Consortium)

## **REACH Authorization of Certain Uses of Chromium Trioxide**

## Question 1: What is the status of these applications for authorization ('AfAs')?

**Response:** Except for functional plating with decorative character (so-called Use 3), all authorizations have been adopted and published, see the Press Release of the CTACSub Consortium of December 22, 2020 for more details Press Release CTACSub Consortium December 22 2020.

The full texts of the authorization decision ('AD') and the authorization numbers are available at Annex 3.

As regards Use 3, CTACSub submitted a Substitution Plan to ECHA on September 24, 2020 as required by the European Commission ("Commission"). ECHA has started to assess this Substitution Plan. Thereafter, the Commission must decide on authorization based on the Opinion of the ECHA SEAC Committee and following vote of the REACH Committee consisting of Member State representatives. We expect this procedure to conclude by mid-year 2021.

Question 2: Will the ADs be valid in the United Kingdom after December 31, 2020 in case there is no trade agreement between the EU and the UK at that time? Will the ADs be valid in the EU after December 31, 2020 if the authorization holder is a UK entity? What about Use 3 in the UK, which has not been decided? What should Downstream Users ('DUs') do?

**Response:** : As the ADs (except for Use 3) have been issued within the EU-UK Withdrawal Agreement's transition period, they are valid in the EU and the UK during the time of transition (until December 31, 2020; unless prolonged) and thereafter. <sup>2</sup> Indeed, according to HSE guidance of December 1, 2020, <sup>3</sup> "EU authorisations granted to UK-based holders before the end of the transition period will be recognised ("grandfathered") by UK REACH. This will include the review period and any conditions attached to the authorisation. This will not incur a fee from HSE".

For these existing authorisations to be grandfathered, UK-based authorization holders will have to provide HSE within 60 days of the end of the transition period with technical information relating to each authorisation they hold. Specifically, according to the HSE "If you are a GB-based downstream user of an EU authorisation granted before the end of the transition period and held by an EU/EEA GB or NI [Northern Ireland]<sup>4</sup>-based business entity, you will be able to continue to use that substance in accordance with that authorisation after

The authorization holders are: Atotech Deutschland GmbH, Boeing Distribution Inc., Chemservice GmbH, CROMITAL S.P.A., Elementis Chromium LLP, MacDermid Enthone GmbH and Prospere Chemical Logistic OÜ.

Please note, however, that any subsequent authorizations granted to that EU/EEA entity after January 1, 2021 and following the review period for the initial authorization will not be valid for the UK users, and any such authorization requests would need to be made to the UK authorities.

Available at: <a href="https://www.hse.gov.uk/brexit/reach-guidance.htm">https://www.hse.gov.uk/brexit/reach-guidance.htm</a>. Please note that the HSE might revise this guidance on December 31, 2020.

Please note that EU REACH will continue to apply to Northern Ireland after the end of the transition period. So EU REACH authorizations granted to NI-based entities will be treated the same in the UK as authorizations of EU-based entities. The only difference is that the draft UK REACH requires that the substance in respect of which the application is made in the UK is a qualifying Northern Ireland good ("QNIG"). A substance is a QNIG if it is a QNIG on its own, or contained in a mixture or article that is a QNIG.

the end of the transition period until the existing EU authorisation relating to the use of the substance ceases to have effect."<sup>5</sup>

Similar to the UK-based authorization holders, within 60 days of the end of the transition period, UK-based DUs will have to provide the HSE with information on their identity, the conditions of the EU REACH authorization, as well as on the identity of their EU supplier.

Therefore, it is clear that the ADs (except for Use 3) granted before the end of the transition period will be recognized in the UK as of January 1, 2021.

As far as the EU authorization holders are UK legal entities, these ADs will become void in the EU at the end of the transition period. Thus, as of January 1, 2021, DUs in the EU can no longer rely on upstream supplies from a UK legal entity. In order for those supplies to continue, the UK authorization holder will have to transfer its authorization (and possibly REACH registration) to an EU legal entity, which then in turn can supply to the EU market as of January 1, 2021.<sup>6</sup>

The situation for Use 3 is different. Although the AfA for Use 3 has been at its final stage in the EU (i.e. Commission level), as noted above, the request of the Commission to provide a Substitution Plan triggers a supplemental opinion by SEAC. That supplemental opinion, however, will only be issued after January 1, 2021. According to the preliminary views of the HSE not published as official guidance, this "hybrid" situation would be treated as an AfA at an early stage of the process. Specifically, the HSE guidance of December 1 stipulates that "If you are based in Great Britain and have submitted an authorisation application under EU REACH but ECHA has not finalised its compiled RAC/SEAC opinions under Article 64(5) by the end of the transition period, you'll need to resubmit your dossier to HSE to continue placing a substance on the GB market or using it in Great Britain after the sunset date."

In other words, a new AfA for Use 3 must be submitted to the HSE after January 1, 2021. In that respect, the UK is moving the latest application date ("LAD") to 18 months after the end of the transition period, provided that the following three cumulative conditions under Article 127GA of the draft UK REACH are met first:

- (i) the application was made to ECHA before the EU LAD;
- (ii) the LAD is before the end of the transition period;
- (iii) the sunset date is on or after 29 March 2017.

Therefore, a new AfA for Use 3 can be filed within the UK 18 months after January 1, 2021. Chromium trioxide can be used for Use 3 during that 18 months period and thereafter whilst the AfA will be pending in the UK and if supplied by one of the UK applicants.

In addition, we have received the following written information from the UK HSE – which is also not captured in official HSE guidance and can therefore not necessarily be relied upon:

Question (2a): Who can file such an application in the UK, the same EU entity which had applied for authorization in the EU or must it be an UK entity (acting on behalf of the EU one)? Are upstream applications permissible in the UK or must a downstream user apply?

<sup>&</sup>lt;sup>5</sup> Available at: <u>https://www.hse.gov.uk/brexit/scenario5.htm.</u>

<sup>&</sup>lt;sup>6</sup> Please note that this will not apply to NI-based authorization holders, as REACH will continue to apply to Apply to NI after the transition period. Therefore, NI-based entities will continue to be treated as EU-based entities under the regime of REACH.

Available at: <a href="https://www.hse.gov.uk/brexit/scenario7.htm">https://www.hse.gov.uk/brexit/scenario7.htm</a>.

**Response:** Only UK entities or ORs can apply. Upstream applications are permissible, but will of course only cover UK downstream users.

Please contact the HSE REACH helpdesk for further information and any update on the information provided above: <u>UKREACHCA@hse.gov.uk</u>

# Question 3: Will the CTACSub members seek to extend their authorizations and thus introduce review reports at the latest 18 months before the end of the respective review periods?

**Response:** CTACSub has decided to continue its work and will file a review report. The details still have to be determined. However, given that the regulatory requirements for obtaining authorization have become ever more demanding over the past six years, the success of the review report will ultimately depend on the quality and representativeness of the information provided by DUs. For this reason, CTACSub will require the factual and financial collaboration of ALL DUs who wish to be covered by the review report (and thus prolongation of the authorization).

As a next step, CTACSub will publish in January 2021 a call for participation of DUs, which will remain open until March 30, 2021. The responses to this call for participation will determine for which uses the review report will be filed. We cannot guarantee now, and pending the results of the call for collaboration, whether review reports will be filed for Uses 3 (functional chrome with decorative character), 4 (aerospace), 5 (miscellaneous surface treatment) and 6 (ETP). We expect that, at least, there will be a larger number of DUs interested in Use 2. Please note that deliveries to DUs that will not collaborate for the review report are expected to stop at the end of the respective review period (September 21, 2024).

Several companies in the Aerospace and Defence ('A&D') sectors have formed a new consortium<sup>8</sup> to support renewal of upstream authorizations for the use of chromates in these sectors only. Relevant portions of CTACSub uses 1, 2, 4 and 5 will be represented.

Question 4: What immediate steps do DUs have to take now (all authorized uses)? Response:

Date	Action	
March 18, 2021	Authorization holders to draw up and distribute (as annexes to safety data sheets) specific exposure scenarios for representative processes, operations and individual tasks. DUs to implement these exposure scenarios without undue delay.	
Around March 22, 20219	DUs to notify uses to ECHA under Art. 66 REACH. DUs also to no their key functionalities and a justification for the necessity of the functionalities to ECHA under Article 66 REACH. The information in be provided in the ECHA notification tool (see <u>Annex 1</u> ).	
June 18, 2021	Downstream users to finish <u>first</u> occupational exposure measurements and air and waste water monitoring campaigns. For the templates to be used for monitoring, please see the GPS and the safety data sheets of the suppliers.	

Betails of the Aerospace and Defence Reauthorization Consortium can be found at https://www.adcr-consortium.eu/

According to Article 66 REACH, DUs must submit the notification within 3 months of the first delivery of the substance after the authorization decision has been published. In order to avoid problems with the date of applicability of this obligation in case a DU is still using up stocks from suppliers with authorization who previously delivered on the basis of a pending application, we recommend, out of an abundance of caution, to file the notification 3 months after the date of publication of the authorization decision. At the date of this Q&A, this publication has not yet occurred. Art. 66(1) REACH: "Downstream users using a substance in accordance with Article 56(2) shall notify the Agency within three months of the first supply of the substance."

December 12, 2021	Downstream users to notify data from occupational exposure measurements and air and waste water monitoring to ECHA in the Article 66 framework. This should be done as an amendment of the earlier Art.
	66 REACH notification.

CTACSub will organize a <u>webinar on January 15, 2021</u>, <u>3pm – 4.30pm (Brussels time)</u> to brief DUs about their obligations from authorization. To sign up to this webinar, please click here:

https://register.gotowebinar.com/register/5569451217499389963. The slides of this webinar will be available in several EU languages. The recording of the webinar can be viewed from www.jonesdayreach.com.

## Question 5: What do DUs have to do in relation to Use 3?

**Response:** CTACSub has submitted a Substitution Plan for Use 3 to ECHA. CTACSub hopes that Use 3 will be authorized in 2021. However, given the continued uncertainty, CTACSub strongly recommend that where feasible, DUs file their own AfAs for Use 3. CTACSub also recommend that companies with Use 3 operations conduct exposure monitoring according to the Good Practice Sheets in the interim period.

## **Question 6: What impact do the ADs have for DUs?**

**Response:** DUs in the supply chain of the applicants can continue their uses until the end of the review periods September 21, 2024 if they can demonstrate to the competent authorities of the EU Member States that they belong to the same supply chain as the authorization holders, their uses fit within the use descriptions of the ADs, they are compliant with the operational conditions and risk management measures set out in the AfAs (see the chemical safety report) and the ADs, and the conditions of the ADs are complied with.

## Question 7: Is there any practical guidance available that DUs can utilize to adapt their operating conditions?

**Response:** YES. CTACSub has developed and published <sup>10</sup> a series of easy to understand illustrative practical Task Sheets ('Good Practice Sheets'; 'GPS') that set out the operational conditions and risk management measures that are recommended when handling chromium trioxide. The GPS also contain advice on personal protective equipment and exposure / emissions monitoring. The GPS do not replace the exposure scenarios in the safety data sheets, but both are consistent. The GPS are just easier to understand for non-experts.

Please see GPS here <u>www.jonesdayreach.com</u>.

# Question 8: How will a DU know whether the chromium trioxide he uses originates (was supplied directly or indirectly) from one or more of the CTACSub authorization holders?

**Response:** The labels and safety data sheets of the substance/preparations will contain authorization numbers. The authorization numbers are 'use'-specific, so DUs need to select for their Article 66 ECHA notification the specific authorization number(s) that correspond to their use. Authorization numbers have the format 'REACH/x/x/x'. In case distributors or formulators supply the substance in mixtures or they have several suppliers for chromium trioxide, the safety data sheets and labels may possibly contain several authorization numbers. It is important that DUs do not accept any deliveries without authorization numbers (unless they receive their chromium trioxide from a supplier whose application is still pending), as they will critically need those numbers for their Article 66 ECHA notification.

<sup>10</sup> https://jonesdayreach.com/substances/

Question 9: Can a DU continue to use a substance that he holds in stock previously received from a supplier who does not hold an authorization (or has no application pending before the latest application date of the respective substance)?

Response: NO.

Question 10: Can a DU continue to use a substance that he holds in stock previously received from a supplier who does not include an authorization number in its label? Response: NO, unless the AfA of this supplier is not decided as yet and was filed before the Latest Application Date.

## Question 11: What does a DU do in case of an inspection?

**Response:** In case of an inspection, the inspector will ask the DU for his Article 66 REACH notification. The DU should also be able to demonstrate and have documented by a self-assessment that his activity falls within the scope of the ADs, that he complies with them including that he applies as a minimum the operational conditions and risk management measures described in the AfAs and ADs. Moreover, he should demonstrate that he is compliant with national legislation on health & safety at the workplace, including occupational exposure limits, the obligation to make a safety assessment for each workplace and to observe the hierarchy of prevention measures for carcinogens at the workplace.

## Annex 1

## Note for Downstream Users on Article 66 REACH notifications

If you are a downstream user ('DU') of chromium trioxide delivered directly or indirectly (e.g. through a formulator or distributor) from any of the CTACSub authorization holders, you are obliged to notify your uses to the European Chemicals Agency ('ECHA') under Article 66 REACH within three months of the publication of the authorization Decision. If you do not comply with this obligation, you might be imposed a fine by your national enforcement authority, and/or the national authority may ask you to stop the use of the substance until you have filed the Article 66 notification with ECHA.

You must submit your Article 66 notification electronically in an on-line form made available by ECHA on its REACH-IT system. This means that as a **first step** – unless you have previously done this already for other reasons - you must 'open a REACH-IT account'. Please note down your User name and Password when opening the account. Once this first step is completed, you can submit as a **second step** your Article 66 notification though REACH-IT. In order to do so, you will need to prepare and have the following minimum information at hand:

- ✓ The name of your company, the address of the sites where the substance is used, and the relevant contact details.
- ✓ The substance and the name of the authorized use, which are identified by the authorization number. You will find the authorization number on the label and/or Safety Data Sheets (SDS) furnished by your substance supplier. The Article 66 notification template provides a drop-down list of all authorization numbers from which you must choose one.
- ✓ A brief explanation of key functionalities required for the DU's use (see the key functionalities per substance and use in the texts of the AD and as set out in Annex 2 and the related justification (why the key functionalities are necessary). This information must be entered into the Art. 66 ECHA REACH IT tool under the section "Further description of your use". Please be very diligent and comprehensive when entering this information. Your supplier may be able to assist you in filling in this information.
- ✓ If you obtain your substance or formulation from more than one supplier, you have to file as many notifications as the number of your suppliers. In order to avoid double counting of tonnage and workers exposed, you have to, in the case of more than one supplier, split the number of workers exposed and the tonnage received so that the figure is accurate.
- ✓ The usual annual volume and the number of workers using the substance (this is voluntary information).
- ✓ A brief additional description of your use (e.g. the type of products you manufacture or the market segments where they are supplied) and any involvement in substitution activities (again, this is voluntary information).

After you are finished with filing your notification, you should write down the 'submission number' and print the report of your notification. You will need the submission number for any future notification updates.

Very importantly, since the authorizations have been granted with conditions, DUs have to comply with these conditions. This means that all DUs who rely on the above authorizations <u>have to conduct annual workers</u> <u>exposure and environmental (air emissions and wastewater) monitoring, and the results of this monitoring must be submitted to ECHA in the Article 66 notification.</u> For applicable dates, please see <u>Q&A above</u>. DUs should use the monitoring templates issued with the SDS and as <u>GPS E2 and E3</u> for compliance with the authorization Decisions' monitoring requirements. CTACSub recommend not to submit

monitoring data under the Article 66 notification in the initial Article 66 notification but only when DUs have conducted their first measurement campaigns with the new monitoring templates. This can be easily done by an 'update' of the earlier Article 66 notification.

Be aware that the monitoring data will have to be uploaded in an Annex of the Article 66 notification.

## **Confidentiality Issues**

Please note that ECHA publishes certain information from the Article 66 notifications, i.e. the substance name, the Member State where the use takes place, whether the notification's status is active or inactive and the tonnage band in an aggregated form, if quantity data was provided. On the other hand, certain information notified under Article 66 is provided **automatically** to the authorization holders, namely the monitoring data referred to above. You can therefore not prevent the monitoring data being submitted to the authorization holders. All you can do is to delete your company identification from the monitoring data, so that your company identity is not revealed to the authorization holders.

DUs have the right to claim confidentiality on their company name, location of the site of use, name of the notified use, brief additional description of use (e.g. the information on key functionalities and justification), and information on substitution activities. If you do not claim confidentiality, ECHA will publish these details too. If you claim confidentiality, you will have to provide justifications for the confidentiality claim to ECHA.

As already noted above, Article 66 notifications can be updated at any time. Therefore, changes can be made including on the data reported and the annexes supplied.

**Further practical guidance** on how to submit your Article 66 REACH notification to ECHA is provided in the following links:

- ECHA Video tutorial on how to submit a downstream user notification HIGHLY RECOMMENDED!!
- <u>Downstream user notifications of authorized uses: Information made public by ECHA</u>

## Annex 2

## **Key Functionalities and Justification thereof**

Key Functionality	Justification of Key Functionality				
Use 2					
Hard chrome plating. Functional chrome plating where any of the following key functionalities is necessary for the intended use					
Wear resistance	Wear resistance is the ability to withstand gradual loss of material due to friction or mechanical stress. This functionality is provided by functional chrome plating and prevents failure of the coated parts, extends their service life and ensure optimal performance.				
Hardness	Hardness is the resistance of solid materials to various kinds of permanent shape changes when a force is applied. Functional chrome coating provides the coated part with high surface hardness and by this to resist against high mechanical pressures occurring during use.				
Layer thickness	Layer thickness is directly related to other key functionalities such as corrosion and wear resistance. Functional chrome coatings can be applied in variable layer thicknesses and by this enable interconnected functionalities to perform optimal during use.				
Corrosion resistance	Corrosion resistance is the ability of a metal to withstand gradual degradation caused by chemical reactions with the environment. Functional chrome coatings provide the coated parts with high resistance to oxidation caused by exposure to humidity, air or other chemicals present during use.				
Coefficient of friction	Friction occurs between contacting surfaces of solids in motion. The coefficient of friction (surface roughness) is a measure for the force required to move the contacting parts against each other. Functional chrome coating provides the coated part with an adjustable but generally low coefficient of friction and by this ensures correct interaction with contacting surfaces during operation, thereby ensuring its optimal performance.				
Effect on surface morphology	Surface morphology describes the surface characteristics of the applied coating that enable specific properties. The presence and density of cracks on the resulting chrome layer has an influence on the performance of the coating and on other functionalities such as corrosion resistance and adhesive properties.				

Key Functionality	Justification of Key Functionality			
Use 4				
Surface treatment aeronautics and aerospace. Surface treatment for applications in the aeronautics and aerospace industries, unrelated to functional chrome plating or functional chrome plating with decorative character, where any of the following key functionalities is necessary for the intended use	Please see examples on site: https://jonesdayreach.com/substances/#supsystic- table-11 under Table IV			
Corrosion resistance/active corrosion inhibition	Corrosion resistance is the ability of a metal to withstand gradual degradation caused by chemical reactions with the environment. Active corrosion inhibition is the ability of a material to spontaneously repair small amounts of chemical or mechanical damage that exposes areas of metal without any surface protection. This functionality extends the service life of parts, prolongs maintenance intervals and enhances on-flight security of air travellers.			
Chemical resistance	Chemical resistance is defined as the ability of solid materials to resist damage by exposure to chemicals such as oils and lubricants.  Resistance to chemicals reduces maintenance costs and enhances safety.			
Hardness	Hardness is the resistance of solid materials to undergo permanent shape changes when a force is applied. High surface hardness is required to withstand high mechanical pressures during operation. This ensures the correct performance of the coated part			
Adhesion promotion (adhesion to subsequent coating or paint)	Adhesion promotion is the ability to enable the correct binding of dissimilar particles or surfaces to one another (for example adhesion of coating to substrate, adhesion of paint to coating and/or substrate). Proper adhesion between coating layers ensures the correct performance of the overall coating and thus of the coated part.			
Temperature resistance	Temperature resistance is the capacity to preserve integrity and performance upon exposure to extreme temperatures. Temperature resistance is required to provide aircraft components with the ability to withstand the effects of repeated exposure to extreme ranges of temperatures during operation.			
Resistance to embrittlement	Resistance to embrittlement is the ability of the coating material to resist exposure to environmental conditions (e.g. temperature, UV light, humidity, etc.) without showing degradation. This functionality is required to			

Key Functionality	Justification of Key Functionality
	avoid failure caused by exposure to the
Wasanasistanas	environment.
Wear resistance	Wear resistance is the ability to resist the
	gradual loss of material due to friction or
	mechanical stress. Wear resistance is required to
	avoid failure arising from progressive material loss due to friction or mechanical stress during
	operation.
Surface properties impeding deposition of	Microorganism present in the environment or on
organisms, layer thickness, flexibility	working fluids might deposit on the surface of
organisms, rayer thickness, hearding	coated parts, where they can promote corrosion.
	This functionality is required to prevent
	corrosion due to the action of microorganisms
	that may grow on the surface of coated parts,
	ensuring their optimal performance.
Layer thickness	The applied coating must have an appropriate
Layer unexitess	thickness to ensure its proper functioning. This
	parameter directly affects the performance of
	the coating and is crucial for enabling other
	functionalities such as corrosion and wear
	resistance.
Flexibility	Flexibility is the ability to expand and contract
rexionity	without failure or breaking. Parts must be
	flexible in order to withstand repeated
	expansion and contraction caused by
	temperature changes.
Resistivity	Resistivity is a measure of a material's ability to
Resistivity	facilitate or impede the flow of electric current.
	This is functionality is required to provide low
	electrical contact resistance, as aerospace
	applications require an electrically conductive
	coating for the respective use.
Us	e 5
Miscellaneous surface treatment. Surface	
treatment (except passivation of tin-plated steel	
(electrolytic tin plating - ETP)) for applications	
in architectural, automotive, metal	
manufacturing and finishing, and general	
engineering industry sectors, unrelated to	
functional chrome plating or functional chrome	
plating with decorative character, where any of	
the following key functionalities is necessary for	
the intended use  Corrosion resistance/active corrosion inhibition	Corrosion resistance is the ability of a metal to
Corrosion resistance/active corrosion ininothon	withstand gradual degradation caused by
	chemical reactions with the environment. Active
	corrosion inhibition is the ability of a material to
	spontaneously repair small amounts of chemical
	or mechanical damage. This is needed to ensure
	or mechanical damage. This is needed to ensure

Key Functionality	Justification of Key Functionality
	performance and extend the service life of the
7 411	treated parts/surfaces.
Layer thickness	The applied coating must have an appropriate
	thickness to ensure its proper functioning. This
	parameter directly affects the performance of the coating and is crucial for enabling other
	functionalities such as corrosion and wear
	resistance.
Adhesion promotion (adhesion to subsequent	Adhesion promotion is the ability to enable the
coating or paint)	correct binding of dissimilar particles or
coating of paint)	surfaces to one another, such as paint particles
	to substrate materials. Proper adhesion between
	coating layers ensures the correct performance
	of the overall coating and thus of the coated
	part.
Resistivity	Resistivity is a measure of a material's ability to
•	facilitate or impede the flow of electric current.
	The high electrical surface resistivity provided
	by chrome coatings prevents the occurrence of
	eddy currents. This is important for energy
	efficiency and optimal performance.
Chemical resistance	Chemical resistance is the ability of solid
	materials to withstand damage by exposure to
	chemicals such as oils and lubricants. This is
	required to protect surfaces against humidity
	and chemicals, enabling correct functionality
	over entire service life.
Wear resistance	Wear is the gradual loss of material due to
	friction or mechanical stress. This functionality
	is required to avoid failure during operation and
The defect on the Abridge	to extend the service life of parts.
Electrical conductivity	Electrical conductivity is a measure of a
	material's ability to conduct electricity. The electrical conductivity of the treated parts and
	surfaces must remain constant to ensure optimal
	performance.
Compatibility with substrate	Coatings and substrate materials must be
Companionity with Substitute	compatible with each other. This is required to
	ensure the correct interaction between the
	applied coating and the treated part/surface,
	ensuring the correct performance of the coating.
Temperature resistance	Temperature resistance is the capacity to
-	preserve integrity and performance upon
	exposure to extreme temperatures. Temperature
	resistance is required to provide components
	with the ability to withstand the effects of
	repeated exposure to extreme ranges of
	temperatures during operation.
Food safety	This parameter relates to the possibility of using
	treated parts and surfaces for the processing of
	foodstuffs. Components intended for contact

Key Functionality	Justification of Key Functionality		
	with foodstuffs have special requirements that must be met to protect consumers.		
Coating tension (coefficient of thermal expansion)	Coating tension has a direct effect on the magnetic properties of the coated substrate. The coating requires a low coefficient of thermal expansion to maintain its tensile strength needed to transmit imparted tension on metal substrate and to reduce magnetostriction. This functionality is highly relevant for energy efficiency and noise reduction of electric components/machines.		
Electric insulation (resistivity)	Electric insulation is the capacity to restrict the flow of electrical current. This parameter influences the performance of parts or surfaces subjected to a magnetic field or electric current. Electrical insulation is required for their correct functioning.		
Deposition speed	The deposition speed describes the rate at which the coating molecules are deposited on the surface of the substrate. The deposition speed of the coating material must be suitable for the application method used. An adequate deposition speed is needed to ensure the continuity of the production process.		
(Thermo) optical properties (visual appearance)	The treated parts/surfaces must not show any aesthetic defects that could suggest failures or deficiencies. This is required to ensure the quality of the coating.		

## Annex 3

## **Commission Implementing Decision**



Brussels, 18.12.2020 C(2020) 8797 final

## **COMMISSION IMPLEMENTING DECISION**

of 18.12.2020

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

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

## **COMMISSION IMPLEMENTING DECISION**

#### of 18.12.2020

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

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

## THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 64(8) thereof, in conjunction with Article 131 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community,

## Whereas:

- (1) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1)(a) of that Regulation.
- (2) On 11 May 2015, LANXESS Deutschland GmbH (acting as only representative of LANXESS CISA (Pty) Ltd), Atotech Deutschland GmbH, Aviall Services Inc<sup>2</sup>, Enthone GmbH<sup>3</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 an application in accordance with Article 62 of Regulation (EC) No 1907/2006 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, namelyarchitectural, 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').

OJ L 396, 30.12.2006, p. 1.

<sup>&</sup>lt;sup>2</sup> Aviall Services Inc. subsequently changed its name to Boeing Distribution Inc.

Enthone GmbH subsequently changed its name to MacDermid Enthone GmbH.

- (3) On 30 September 2016, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and the Committee for Socioeconomic Analysis (SEAC) of the European Chemicals Agency<sup>4</sup> ('the Agency') and sent to it pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) On 21 March 2018 the Agency received a notification that the application had been transferred from the original applicant BONDEX TRADING LTD to Prospere Logistic Baltic OÜ. On 14 October 2019 the Agency received notification that the application had been further transferred to Prospere Chemical Logistic OÜ. In its assessment, the Agency concluded that the notified changes had no implications for the RAC and SEAC opinions. The Commission agrees with that conclusion.
- (5) On 27 March 2019, the European Parliament adopted a resolution<sup>5</sup> concerning the draft of this Decision for a use of chromium trioxide. The Commission took note of that resolution.
- (6) On 28 February 2020 the Agency received a notification that the application had been transferred from the original applicant LANXESS Deutschland GmbH to Chemservice GmbH. In its assessment, the Agency concluded that the notified change had no implications for the RAC and SEAC opinions. The Commission agrees with that conclusion.
- (7) The Commission's assessment of use 3 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, 5 and 6, as well as use 1 in relation to the formulation of mixtures for uses 2, 4, 5 and 6.
- (8) RAC concluded in its opinions 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.
- (9) In its opinions on uses 1, 2, 4 and 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.
- (10) Concerning uses 1, 2, 4 and 5, RAC further concluded that there are significant uncertainties regarding worker exposure due to limited availability of measured exposure data. RAC 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

https://www.europarl.europa.eu/doceo/document/TA-8-2019-0317 EN.html

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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 applicants have not been able to fully assess the combined exposure related to all those tasks. Nevertheless the Commission notes that those uncertainties did not prevent SEAC from further analysing the application.

- (11) Concerning uses 1, 2, 4 and 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 provided assessment of risks to the general population via the environment 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.
- (12) In its opinions on uses 1, 2, 4 and 5, due to the uncertainties in the assessment of risks to workers and to the general population via the environment, RAC recommended
- to workers and to the general population via the environment, RAC recommended imposing additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with that conclusion.
- In its opinion on use 6, RAC concluded that the risk management measures and (13)operational conditions as described in the application, 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 concluded that the description of contributing scenarios and the exposure assessment in the application would have benefitted from a more specific assessment for use 6 and that there are some uncertainties related to the frequency and combination of tasks performed by individual workers but the impact of those uncertainties on total exposure were considered to be
- (14) In its opinion on use 6, due to the uncertainties concerning 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 the general population via the environment, RAC recommended imposing additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with that conclusion.

- In its opinions as regards uses 1, 2, 4, 5 and 6 of chromium trioxide as described in the (15)application 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 on a worst case scenario basis. Other benefits, based on the avoided negative impacts due to disruptions in the supply chain, further strengthen that conclusion. Concerning uses 2, 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 the social costs due to job losses alone, clearly outweigh the monetised human health impacts, which are calculated on a worst case scenario basis. 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 for uses 2, 4, 5 and 6, as well as for use 1 in relation to the formulation of mixtures for uses 2, 4, 5 and 6.
- (16)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 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 difference between the socio- economic 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, 4, 5 and 6. 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.
- (17) In its opinion on use 1, considering that chromium trioxide has no independent function at the stage of formulation and consequently an assessment of the feasibility of alternatives for that use is irrelevant, SEAC concluded that there are no suitable alternative substances or technologies. The Commission, having evaluated SEAC's assessment, concurs with that conclusion as regards the formulation of mixtures for uses 2, 4, 5 and 6.
- (18) In its opinions on uses 2, 4 and 5, SEAC concluded that there are no suitable alternative substances or technologies. However, due to the very broad scope of the uses applied for, 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 those uses. The Commission concurs with SEAC's conclusion.
- (19) In order to ensure that the authorisation covers only those uses for which no suitable alternatives are available, it is necessary to further specify the description of uses 2, 4

and 5 by aligning it with the conclusions of the analysis of alternatives as presented in the application and as assessed by SEAC. The Commission considers that the applicants have discharged their burden of proof in demonstrating the absence of suitable alternatives as regards uses 2, 4 and 5, only with regard to such limited scope of the uses.

- (20) Therefore, the description of uses 2, 4 and 5 should be further specified by referring to uses where any of the following key functionalities 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/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.
- Concerning use 4, the application refers to the 'inhibition of biological organisms, biostatic properties' as key functionalities for achievement of which the use of chromium trioxide is necessary. Such a reference in the description of use may be understood to cover 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>6</sup>. In accordance with Article 17(1) of Regulation (EU) No 528/2012, chromium trioxide cannot be placed on the market, nor used as a biocidal product as it has not been authorised under that Regulation. In addition, in accordance with Article 56(4)(b) of Regulation (EC) No 1907/2006, uses of substances in biocidal products are not to be authorised under that Regulation. To avoid that uses of chromium trioxide as a biocidal product are understood to be covered by this authorisation and to reflect the factual situation, the reference to '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.
- (22) 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 SEAC's assessment, and taking the above considerations into account, agrees with the conclusion that there are no suitable alternative substances or technologies for uses 2, 4 and 5.
- (23) 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.
- (24) Concerning use 5, 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 articles for supply to the general public.

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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).

- (25) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise use 6 of chromium trioxide as applied for, and uses 1, 2, 4, 5 of chromium trioxide 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, 4, 5 where the specified key functionalities are not necessary for the use.
- (26) 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 assessment 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.
- (27) Furthermore, in order to facilitate the enforcement of this Decision, with regard to uses 2, 4 and 5, it is necessary to require the authorisation holders' downstream users to include in the notification sent to the Agency pursuant to Article 66(1) of Regulation (EC) No 1907/2006, an explanation of the key functionalities listed in Article 1(1) of this Decision which are necessary for their use, including a justification why they are necessary for that use for that use.
- In its opinions, SEAC recommended the review period referred to in Article 60(9)(e) of (28)Regulation (EC) No 1907/2006 to be set at seven years for uses 1, 2 and 4 and at four years for uses 5 and 6. The Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments. Concerning use 1, 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 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 an authorisation is not granted. Concerning uses 2, 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 additional conditions and monitoring arrangements imposed by this Decision to address those concerns, the time necessary to implement and industrialise 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 the authorisation is not granted. 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, the time necessary to implement and industrialise 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 an authorisation is not granted.
- 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.

- (30) 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 time-limits for compliance with such conditions established by this Decision, the review period recommended by the SEAC for uses 5 and 6 would make it practically impossible for the authorisation holders to submit a review report within the time-limits in the present case. Therefore, for those uses, it is appropriate to provide for a 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. Nevertheless, taking into account the delay in adopting this Decision, it is also appropriate to align the expiration date of the review period of uses 5 and 6 to the one set out for uses 1, 2 and 4.
- (31) The language used to describe 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.
- (32) This Decision does not affect the obligation of the authorisation holders 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 holders under Article 60(10) of that Regulation to ensure that the exposure 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 Council<sup>7</sup> 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 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/EEC<sup>8</sup>, 92/85/EEC<sup>9</sup>, 94/33/EC<sup>10</sup>, 98/24/EC<sup>11</sup> and Directive 2004/37/EC, nor does it affect any national binding occupational limit values which may be stricter than the applicable Union limit values.
- (33) 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

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).

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).

<sup>11</sup> 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).

Council<sup>12</sup> or Directive 2010/75/EU of the European Parliament and of the Council<sup>13</sup> nor any obligation to comply 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<sup>14</sup> or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council<sup>15</sup>. Compliance with the provisions of this Decision should 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.

- (34) Pursuant to Article 127(1) of the Withdrawal Agreement, Union law is applicable to and in the United Kingdom during the transition period unless otherwise provided in that Agreement. Under Article 126 of the Agreement, the transition period ends on 31 December 2020. It may, however, be extended for up to 1 or 2 years through a single decision adopted in accordance with Article 132 of the Withdrawal Agreement.
- (35) One of the adressees of this Decision is a legal entity established in the United Kingdom. Regardless of the period of validity pursuant to this Decision, the Decision can therefore only apply for the duration of that transition period.
- (36) 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

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

Authorisation number	Authorisation holder	Authorised use
REACH/20/18/0	Chemservice GmbH	Formulation of mixtures exclusively for uses REACH/20/18/7 to REACH/20/18/34
REACH/20/18/1	Atotech Deutschland GmbH	
REACH/20/18/2	Boeing Distribution Inc.	
REACH/20/18/3	Prospere Chemical Logistic OÜ	

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).

REACH/20/18/4	CROMITAL S.P.A.			
REACH/20/18/5	Elementis Chromium LLP			
REACH/20/18/6	MacDermid Enthone GmbH			
REACH/20/18/7	Chemservice GmbH	Functional chrome plating where any of the following key functionalities is		
REACH/20/18/8	Atotech Deutschland GmbH	necessary for the intended use: wear resistance, hardness, layer thickness,		
REACH/20/18/9	Boeing Distribution Inc.	corrosion resistance, coefficient of friction, or effect on surface		
REACH/20/18/10	Prospere Chemical Logistic OÜ	morphology		
REACH/20/18/11	CROMITAL S.P.A.			
REACH/20/18/12	Elementis Chromium LLP			
REACH/20/18/13	MacDermid Enthone GmbH			
REACH/20/18/14	Chemservice GmbH	Surface treatment for applications in the aeronautics and aerospace		
REACH/20/18/15	Atotech Deutschland GmbH	industries, unrelated to functional chrome plating or functional chrome		
REACH/20/18/16	Boeing Distribution Inc.	plating with decorative character, where any of the following key		
REACH/20/18/17	Prospere Chemical Logistic OÜ	functionalities is necessary for the intended use: corrosion resistance /		
REACH/20/18/18	CROMITAL S.P.A.	active corrosion inhibition, chemical resistance, hardness, adhesion		
REACH/20/18/19	Elementis Chromium LLP	promotion (adhesion to subsequent coating or paint), temperature		
REACH/20/18/20	MacDermid Enthone GmbH	resistance, resistance to embrittlement, wear resistance, surface properties impeding deposition of organisms, layer thickness, flexibility, and resistivity		
REACH/20/18/21	Chemservice GmbH	Surface treatment (except passivation of tin-plated steel (electrolytic tin		
REACH/20/18/22	Atotech Deutschland GmbH	plating - ETP)) for applications in architectural, automotive, metal		
REACH/20/18/23	Boeing Distribution Inc.	manufacturing and finishing, and general engineering industry sectors,		
REACH/20/18/24	Prospere Chemical Logistic OÜ	unrelated to functional chrome plating or functional chrome plating		
REACH/20/18/25	CROMITAL S.P.A.	with decorative character, where any of the following key functionalities is		
REACH/20/18/26	Elementis Chromium LLP	necessary for the intended use: corrosion resistance/ active corrosion		
REACH/20/18/27	MacDermid Enthone GmbH	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

REACH/20/18/28	Chemservice GmbH	Passivation of tin-plated (electrolytic tin plating - ETP)	
REACH/20/18/29	Atotech Deutschland GmbH	(electrorytic till platting - E11)	
REACH/20/18/30	Boeing Distribution Inc.		
REACH/20/18/31	Prospere Chemical Logistic OÜ		
REACH/20/18/32	CROMITAL S.P.A.		
REACH/20/18/33	Elementis Chromium LLP		
REACH/20/18/34	MacDermid Enthone GmbH		

- 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 the aeronautics and aerospace industries, unrelated to functional chrome plating or functional chrome plating with decorative character, where none of the key functionalities listed in paragraph 1 regarding that use is necessary for the use.
- 4. An authorisation for the use of chromium trioxide is not granted for surface treatment for applications (except passivation of tin-plated steel (electrolytic tin plating ETP)) in architectural, automotive, metal manufacturing and finishing, and general engineering industry sectors, unrelated to functional chrome plating or functional chrome plating with decorative character, where none of the key functionalities listed in paragraph 1 regarding that use is necessary for the use.
- 5. The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety reports<sup>16</sup>, and to the conditions laid down in this Decision.

#### Article 2

1. The conditions set out in paragraphs 2 to 9 shall apply to the authorisation bearing numbers REACH/20/18/0 to REACH/20/18/27.

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2. The authorisation holders 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 to control worker exposure to chromium (VI) and its emissions into the environment, representative for all sites at which the authorised uses take place, 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 specific exposure scenarios in accordance with Article 5 of Directive 2004/37/EC. The authorisation holders shall document and justify the selection of risk management measures and shall make available the relevant documents to the competent authorities of the Member State where an authorised use takes place upon request.

- 3. The authorisation holders shall make available the specific exposure scenarios 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 18 March 2021. The authorisation holders 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 holders shall verify and validate the specific exposure scenarios referred to in paragraph 2 at the latest on 18 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, relating to all processes described for the authorised uses. The validated and verified exposure scenarios shall immediately be made available to the downstream users.
- 5. The information to be made available to downstream users as referred to in paragraphs 3 and 4 shall include detailed guidance on how to select and apply risk management measures. The authorisation holders and the downstream users shall submit that information to the competent authorities of the Member States where the authorised uses take place upon request.
- 6. The authorisation holders 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 Directive 2004/37/EC. The first measurements shall be performed without delay and at the latest on 18 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 those tasks:
    - (iii) the number of workers potentially exposed;

- (b) At least annual monitoring programmes for chromium (VI) emissions into 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 holders 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 authorisation holders and the downstream users shall document the results of those measurements and of any action taken following the review and shall make them available, upon request, to the competent authorities of the Member State where the authorised uses take place.
- 8. The authorisation holders 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 in accordance with paragraph 9. The authorisation holders shall provide the report template 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 referred to in paragraph 6, including the contextual information related to each set of measurements, in the format of the template referred in paragraph 8, for the first time by 18 December 2021, for transmission to the authorisation holders for the purpose of verifying and validating the exposure scenarios as referred to in paragraph 4 and for the preparation of the review report.

#### Article 3

The authorisation bearing numbers REACH/20/18/14 to REACH/20/18/27 shall be subject to the following condition: as regards spraying operations, the downstream users 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/20/18/21 to REACH/20/18/27 shall be subject to the condition that the authorisation holders and the 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 authorisation bearing numbers REACH/20/18/7 to REACH/20/18/27, 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 the Article 1(1) which are necessary for their use, including a justification why such key functionalities are necessary for that use.

#### Article 6

- 1. The conditions set out in paragraphs 2 to 4 shall apply to the authorisation bearing numbers REACH/20/18/28 to REACH/20/18/34.
- 2. The downstream users shall implement best practices to reduce workplace exposure to chromium trioxide and emissions into the environment to as low a level as technically and practically feasible, including the use of closed systems and automation, whenever possible. Where it is not possible to use closed systems and automation, the downstream users 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 systems can only be justified in exceptional circumstances where use of LEV systems is technically impossible. The downstream users shall be able to provide a justification when not using the LEV systems. The downstream users shall make available the information on LEV systems put in place in the installations where the authorised uses are taking place and on their maintenance to the competent authorities of the Member States.
- 3. Where RPE is needed to control exposure to chromium trioxide, it shall be used in accordance with standard procedures for use and maintenance. Those procedures shall include procedures for fit testing of RPE masks, applied in accordance with relevant standards, shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the RPE.
- 4. The 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 7

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 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.

## Article 8

- 1. The monitoring arrangements set out in paragraphs 2 to 5 shall apply to the authorisation bearing numbers REACH/20/18/28 to REACH/20/18/34.
- 2. The authorisation holders and the downstream users shall implement at least annual air monitoring programmes on occupational exposure 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 18 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 those tasks;
- (iii) the number of workers potentially exposed.
- 3. The authorisation holders and the downstream users shall implement monitoring programmes for chromium (VI) emissions into 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 sites where relevant measurements are carried out.
- 4. The authorisation holders and their downstream users shall use the information gathered via the measurements referred to in paragraphs 2 and 3 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.
- 5. The downstream users shall make available to the Agency the information collected from the monitoring programmes referred to in paragraph 2 and 3, including the contextual information associated to each set of measurements, for the first time by 18 December 2021, 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 the downstream users, upon request, to the competent authorities of the Member States where an authorised use takes place.

## Article 9

Where the authorisation holders submit a review report, it shall include the following information:

- (a) as regards authorisation bearing numbers REACH/20/18/0 to REACH/20/18/27, the specific exposure scenarios and the documents related to the selection of the risk management measures 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) as regards authorisation bearing numbers REACH/20/18/28 to REACH/20/18/34, the information gathered via the measurements and contextual information referred to in Article 8(2) and (3);
- (c) a refined assessment of the exposure of the general population to chromium (VI) via the environment, as well as of the resulting risks. The 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<sup>17</sup> and those 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 members of the general population via the environment, including the oral route, shall be included in the assessment.

#### Article 10

Upon request, the authorisation holders 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 11

This Decision is addressed to:

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- 1. Chemservice GmbH, Herrnsheimer Hauptstrasse 1b 67550 Worms, Germany;
- 2. Atotech Deutschland GmbH, Erasmusstraße 20, 10553, Berlin, Germany;
- 3. Boeing Distribution Inc., Schillingweg 40, 2153PL, Nieuw-Vennep, Noord-Holland, Netherlands;
- 4. Prospere Chemical Logistic OÜ, Lao 21, 74114 Maardu, Estonia;
- 5. CROMITAL S.P.A., Strada Quattro, Pal. A7, 20090, Assago (MI), Italia;
- 6. Elementis Chromium LLP, Eaglescliffe, TS16 0QG, Stockton on Tees, United Kingdom;
- 7. MacDermid Enthone GmbH, Elisabeth-Selbert-Str. 4, 40764, Langenfeld, Germany. Done at Brussels, 18.12.2020

For the Commission Thierry BRETON
Member of the Commission

CERTIFIED COPY For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION

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

## **Annex to the Commission Implementing Decision**



Brussels, 18.12.2020 C(2020) 8797 final

ANNEX

## **ANNEX**

to the

## **COMMISSION IMPLEMENTING DECISION**

partially granting an authorisation for certain uses of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Chemservice 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(5) of authorisation bearing numbers REACH/20/18/14 to REACH/20/18/20

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)	< 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 (minimum APF 400), effectiveness 99.75%	good natural ventilation and medium level of containment  good natural ventilation and low level of containment  good natural ventilation
(PROC 8b) Re-filling of baths – liquids		mixture: substantial (10- 50%)	~ 1	0.11.0	
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 (minimum APF 400), 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 (minimum APF 400), effectiveness 99.75%	good natural ventilation, closed system
WCS 25 (PROC 8b) Cleaning and	< 15 min	Cr (VI) in mixture: minor (5-10%)	No		specialized ventilation: more than 10 ACH, indoor

maintenance				in spray
of equipment – tools				room
cleaning				
(spray cabin)				
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(5) of the authorisation bearing numbers REACH/20/18/21 to REACH/19/18/27

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	< 30 min (combined for WCS 2, 4 and 6)	Cr(VI) in mixture: substantial (10-50%)	yes	yes, full-face- mask with A2P3 filter (minimum APF 400), effectiveness 99.75%	good natural ventilation and medium level of containment good natural
(PROC 5) Mixing-liquids WCS 6 (PROC 8b)		mixture: substantial (10-50%) Cr(VI) in mixture:			ventilation and low level of containment good natural ventilation
Re-filling of 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 (minimum APF 400), 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 (minimum APF 400), effectiveness 99.75%	good natural ventilation, closed syste m
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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