

April 16, 2019

(updated)

## Questions & Answers

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

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

##### **Question 1: What is the status of these applications for authorizations (“AfA”)?**

**Response:** The REACH Committee of the European Commission approved the CTACSub authorization Decision on February 15, 2019. The Commission was therefore expected to issue the Decision towards the end of March.<sup>2</sup> However, on March 7, the EU General Court issued a ruling (T-837/16) on another authorization which sets strict conditions for the future Commission decision making. Pursuant to the court ruling and a European Parliament Resolution of March 27, 2019 requesting that the Commission withdraw the CTACSub Decision and submit a new draft, the Commission re-discussed the draft authorization Decision at the REACH Committee meeting on April 11/12, along with other draft authorization decisions to evaluate the impact from the General Court ruling. It is our understanding that no decisions were taken. New information is expected at the latest at the next REACH Committee meeting mid-June. In view of the above developments, the below timelines (which are now based on the potential scenario of a new vote at the June REACH Committee meeting) may again slip.. **You may therefore expect updates to Q1 and other Qs at any time.**

##### **Question 2: Will the Commission reject the applications for authorization after the General Court ruling and the European Parliament Resolution?**

**Response:** First, the European Parliament Resolution, which was adopted with only 309 votes in favour and 286 votes against, has no binding force on the Commission. However, the Commission will re-evaluate its work and check whether the draft authorization Decision is still correct and whether it complies with the principles set up by the General Court. Given that the authorization is supported by ECHA’s RAC and SEAC committees and most of the EU Member States (24 out of 28 votes in favour at the REACH Committee in February), we expect that the Commission will continue to propose authorization. There could be, however, some changes to the text, to reflect the General Court ruling. We do not expect changes to the review periods.

##### **Question 3: Assuming the Member States will approve and the Commission will adopt the authorization decisions, what is the timing?**

**Response:** If adopted in June, we can expect notification of the authorization Decision by mid-July. Assuming the review periods stay as is, the use of chromium trioxide would be authorized until mid-July 2023<sup>3</sup> for Uses 3 (functional plating with decorative character), 5 (miscellaneous surface treatment) and 6 (passivation of tin-plated steel (ETP)), and until September 21, 2024 for Uses 1 (formulation), 2 (functional plating) and 4 (surface treatment in the aeronautics and aerospace industry).

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<sup>1</sup> Members of the CTACSub Consortium are: Atotech Deutschland GmbH; Aviall Services Inc; Prospere Logistic Baltic OÜ (as legal successor to BONDEX TRADING LTD), in its legal capacity as Only Representative of Aktyubinsk Chromium Chemicals Plant, Kazakhstan; CROMITAL S.P.A. in its legal capacity as Only Representative of Soda Sanayii A.S.; Elementis GmbH in its legal capacity as Only Representative of Elementis Chromium Inc.; Enthone GmbH (now MacDermid Enthone); LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd.

<sup>2</sup> Link to the authorization Decisions is to be inserted when they are published in the EU Official Journal (i.e. –mid-July 2019). To view the current draft authorization Decision approved by the REACH Committee on February 15, 2019, please refer to CTACSub Consortium Press release of February 21, 2019, available at: <http://www.jonesdayreach.com/SitePages/News.aspx>

<sup>3</sup> This is counted as four years following the adoption of the authorization Decisions (see footnote 2).

Any company that seeks to continue its use beyond the respective review period can either introduce its own application for authorization as soon as possible (ideally 24 months before the end of the respective review period so as to account for sufficient time for European Union decision making) or it should seek assurances from its suppliers that they will introduce review reports to extend authorization.

**Question 4: (No-deal Brexit) What will happen with a UK downstream user relying on a REACH authorization granted to an EU-based entity prior to the UK's withdrawal from the EU? What should the downstream user do?**

**Response:** A UK downstream user of a REACH authorization held by an EU-based company can continue to use the relevant substance in accordance with the conditions of the authorization provided that he/she within **60 days** of the UK's withdrawal from the EU:

- Submits to the UK Health and Executive ("HSE") the information that he/she is an existing authorized downstream user under REACH with reference to the particular substance; and
- Notifies the HSE of: (i) the existing REACH authorization; (ii) the conditions (if any) laid down in the existing authorization; (iii) the identity of the EU-based supplier.

**Question 5: (No-deal Brexit) What will happen with a UK downstream user relying on a REACH AfA by an EU-based company where the European Chemicals Agency ("ECHA") has adopted its final opinion but the European Commission has not made a final decision – e.g. potentially the case of the CTACSub AfA? What should downstream users do?**

**Response:** According to HSE's advice, there is currently no legal protection (possibility of continued use) for UK downstream users relying on an ongoing AfA by an EU-based company. Such protection only exists for UK downstream users of UK applicants that had previously filed an EU AfA and have received RAC/SEAC opinions (such UK applicants must notify the UK Secretary of State for the Department of Environment, Food & Rural Affairs ("Defra")). Moreover, there is currently no fast-tracking procedure foreseen for AfAs previously introduced at EU level by EU/EEA based applicants and having received RAC/SEAC opinions. These applicants would have to appoint an UK entity and introduce a new application in the UK. To the contrary, previous EU AfAs introduced by UK applicants and having received RAC/SEAC opinions will be fast tracked in the UK.

For all of the above reasons, we therefore recommend to UK downstream users of EU/EEA applicants that they contact HSE to determine the way forward.

Further information on Question 4 and Question 5 is provided in:

- The Draft UK-REACH Statutory Instruments, Title 14A, available at: [http://www.legislation.gov.uk/ukdsi/2019/9780111180358/pdfs/ukdsi\\_9780111180358\\_en.pdf](http://www.legislation.gov.uk/ukdsi/2019/9780111180358/pdfs/ukdsi_9780111180358_en.pdf)
- Defra "*UK REACH Guidance if there is no Brexit deal*", Scenarios 5 and 7, available at: <http://www.hse.gov.uk/brexit/uk-reach-additional-guidance.pdf>,
- HSE website at: <http://www.hse.gov.uk/brexit/reach.htm> and <http://www.hse.gov.uk/brexit/further-info.htm>

The HSE REACH helpdesk can be contacted at: <http://www.hse.gov.uk/reach/helpdesk.htm>

**Question 6: Will the upstream suppliers seek to extend their authorizations and thus introduce review reports at the latest 18 months before the end of the respective review periods?**

**Response:** The authorization holders have not yet decided this. Their decision will depend, among others, on the following factors:

- ✓ The consumption of the substance in the EU;

- ✓ The availability of comprehensive exposure and emissions monitoring data from the downstream users reporting to ECHA by July 2020<sup>4</sup>;
- ✓ Organization and financing of a collaboration;
- ✓ The impact of the General Court judgement on the Commission's decision making practice.

**Question 7: What impact do the authorization decisions have for downstream users?**

**Response:** Downstream users in the supply chain of the applicants can continue their uses until the end of the respective review periods (see above) 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 decisions, they are compliant with the operational conditions and risk management measures set out in the applications for authorization and the decisions, and the conditions of the decisions are complied with.

**Question 8: What immediate steps do downstream users have to take now?**

**Response:** Once the authorization Decisions will have been issued, as a next immediate step, downstream users of chromium trioxide must notify their chromium trioxide uses to the European Chemicals Agency (ECHA) under Article 66 REACH within three months of the publication of the authorization Decisions in the EU Official Journal, thus at the latest on or around mid-October, 2019. 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 chromium trioxide until you have filed the Article 66 notification with ECHA. Please see chart below on actions and timelines.

<b>Date<sup>5</sup></b>	<b>Action</b>
July 15, 2019	Authorization decision notified to applicants ( <b>date estimated</b> )
October 15, 2019	Downstream users to scrutinize new specific exposure scenarios for representative processes, operations and individual tasks to be drawn up by suppliers (as annexes to safety data sheets)
October 15, 2019	Downstream users to notify uses to ECHA under Article 66 REACH
January 15, 2020	Downstream users to finish first exposure measurement campaigns
As of July 15, 2019	Downstream users to implement monitoring programs for Chromium (VI) emissions to wastewater and air from LEV
July 15, 2020	Downstream users to notify data from exposure measurements and air and waste water monitoring to ECHA

For further guidance on how to submit your Article 66 notification, please refer to the 'Note for Downstream Users on Article 66 REACH notifications' attached as Annex 1 to this Q&A document.

**Question 9: How will a downstream user know whether the chromium trioxide he uses originates (was supplied directly or indirectly by) from one or more of the 7 CTACSub authorization holders?**

**Response:** The labels and safety data sheets of chromium trioxide will contain authorization numbers. The authorization numbers are 'use'-specific, so downstream users 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 (or chromium trioxide

<sup>4</sup> Estimated date. One year after publication of authorization decision.

<sup>5</sup> All dates are estimated. Final dates depend on date of notification/publication of authorization decisions, as the case may be.

in mixture), the safety data sheets and labels may possibly contain several authorization numbers. It is important that downstream users 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 (see above).

**Question 10: What authorization number should the downstream user notify to ECHA in case he uses up chromium trioxide supplied before the date of authorization?**

**Response:** As a matter of practicality, he should use the authorization number mentioned in the next delivery of his usual supplier.

**Question 11: Can a downstream user continue to use chromium trioxide that he holds in stock previously received from a supplier who does not hold an authorization (or has no application pending introduced before March 21, 2016)?**

**Response:** NO.

**Question 12: What does a downstream user do in case of an inspection?**

**Response:** First, please note that the REACH Forum<sup>6</sup> has decided that compliance with REACH authorizations for chromates will be a priority of national enforcement in 2019. Downstream users should therefore expect an inspection at the latest in 2019. Several Member States (including France and the United Kingdom) started inspection campaigns already in 2017, immediately after the Sunset Date had passed.

In case of an inspection, the inspector will ask the downstream user for his Article 66 REACH notification. The Downstream user should also be able to demonstrate and have documented by a self-assessment that his activity falls within the scope of the authorization decisions, and that he applies as a minimum the operational conditions and risk management measures described in the applications and decisions. 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.

**Question 13: Is there any practical guidance available that downstream users can utilize to adapt their operating conditions?**

**Response:** YES. CTACSub has developed and published<sup>7</sup> a series of easily comprehensible 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.

**Question 14: Do the authorization Decisions impose specific conditions on 'articles for supply to the general public'?**

**Response:** YES. An authorization holder and its downstream users must ensure that there is no chromium (VI) above the detectable level present in articles for supply to the general public under Use 5. Please note that the CTACSub Consortium will issue recommendations for test standards to use to prove that no chromium (VI) residues are present.

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<sup>6</sup> Article 86 REACH. Consisting of national inspectors. Responsible for coordination of enforcement across the EU. <https://echa.europa.eu/-/more-enforcement-on-authorisation-and-registration-coming-up-for-2019>

<sup>7</sup> See <http://www.jonesdayreach.com/SitePages/Home.aspx>

‘Articles for supply to the general public’ have been defined by the European Commission<sup>8</sup> as ‘articles put at the disposal of the general public’, regardless of the type of ownership (public or private) or the specific type of transaction by which the objects were put at the disposal of the general public. ‘Supply to the general public’ excludes articles intended for professional use, since according to ECHA the concept of ‘professional use’ should be understood “[...] as a characteristic to distinguish between use: i) at industrial sites and ii) uses outside industrial sites (but not consumers or general public).”<sup>9</sup>

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<sup>8</sup> See document CA/30/2016, 21st Meeting of Competent Authorities for REACH and CLP (CARACAL), available at: <https://circabc.europa.eu/ui/#>

<sup>9</sup> ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R. 12: Use description, available at: [https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r12\\_en.pdf](https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf)

## ANNEX 1

### Note for Downstream Users on Article 66 REACH notifications

April 16, 2019

#### CTACSub Consortium

The European Commission is expected to publish around July 15, 2019 the REACH authorization decisions for the six uses of chromium trioxide (EC 215-607-8; CAS 1333-82-0) applied for in May 2015 by the following seven authorization holders:

- Atotech Deutschland GmbH;
- Aviall Services Inc;
- CROMITAL S.P.A in its legal capacity as Only Representative of Soda Sanayii A.S.;
- Elementis GmbH 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; and
- Prospero Logistic Baltic OÜ in its legal capacity as Only Representative of Aktyubinsk Chromium Chemicals Plant, Kazakhstan.<sup>10</sup>

**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 seven companies above, you are obliged to notify your chromium trioxide uses to the European Chemicals Agency (ECHA) under Article 66 REACH within three months of the publication of the authorization decisions in the EU Official Journal, thus at the latest on or around October 15, 2019.** 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 chromium trioxide 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 through 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.
- ✓ The usual annual volume and the number of workers using the substance (this is voluntary information).
- ✓ If you obtain your chromium trioxide or solution containing chromium trioxide 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.

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<sup>10</sup> For further information on the authorization decisions, please see CTACSub Consortium Press release of February 21, 2019, available at: <http://www.jonesdayreach.com/SitePages/News.aspx>

- ✓ 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 that rely on the above authorizations **have to conduct annual workers exposure and environmental (air emissions and waste water) monitoring, and the results of this monitoring must be submitted to ECHA in the Article 66 notification.** However, the first notification of workers exposure and environmental information is not due until 12 months after the publication of the authorization decisions, so on and around **July 15, 2020**. Please note that the CTACSub Consortium will issue a reporting format for exposure monitoring at the beginning of **July 2019**. CTACSub recommends to use this monitoring format for compliance with the authorization decisions’ monitoring requirements. Therefore, CTACSub recommends not to submit monitoring data under the Article 66 notification in the initial (October 15, 2019) notification but only later, when the new monitoring format will be available and the DUs have conducted their first measurement campaigns (which must be done by January 15, 2020)<sup>11</sup>. 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, 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!!\*\*](#)
- [Downstream user notifications of authorized uses: Information made public by ECHA](#)

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<sup>11</sup> Estimated date – 6 months after publication of authorization decisions.