

Questions & Answers

CCST Consortium

Applications for REACH Authorization of Miscellaneous Chromates in the Aeronautics Industries and of Sodium dichromate for the electrolytic passivation of tin plated steel for the packaging industry ('ETP')

September 23, 2019

Question 1: What is the status of these applications for authorizations?

Response: The REACH Committee of the European Commission approved the CCST authorization Decisions for five of the six substances on September 17, 2019. The European Commission ('Commission') must now formally adopt them, notify them to the applicants, and publish them. This is expected to happen by the end of October. As regards one of the substances for which an application for authorization was filed with ECHA later, namely Pentazinc chromate octahydroxide, the Commission has not finished its work. The CCST Consortium hopes that the Commission will forward this file to a vote in the REACH Committee on November 19/20 2019, or possibly February 3/4, 2020.

Question 2: What are the review periods granted? How long can downstream users ('DU') use the substances?

Response: In all cases except for ETP, the review period is 7 years (for ETP 4 years as of date of adoption). For those substances for which the Sunset date passed on September 21, 2017, namely sodium dichromate and potassium dichromate, the review period is set in the text of the draft decision at **September 21, 2024**. For the other substances, the review period is set in the text of the draft decision at **January 22, 2026**. In all cases, the review reports must be filed with ECHA at a minimum 18 months before the end of the review period if the use should continue beyond the above dates. DUs may therefore continue to use the substances as a minimum until the end of the respective review periods, provided they are within the scope and comply with the respective conditions.

Question 3: Will the EU authorizations also be valid in the United Kingdom in case of a so-called 'No deal Brexit'?

Response: A UK DU 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 within **60 days** of the UK's withdrawal from the EU:

- Submits to the UK Health and Executive ('SE') the information that he is an existing authorized DU 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; and (iii) the identity of the EU-based supplier.¹

Note: In case the Commission will not have issued the authorizations by the Brexit date, a different regime will apply. The initial legislative proposal in the UK did not provide for any transitional period for UK DUs relying on an ongoing application for authorization ('AfA') by an EU-based company. However, the latest UK Statutory Instrument on REACH 'EU-Exit' legislation (to be signed into law after October 4, 2019) would postpone for pending EU AfAs the EU so-called Latest application dates and Sunset dates by 18 months from the UK exit day to allow UK importers and DUs to file new UK authorization applications and in the meantime continue their use in the UK pending UK authorization. See here.² In other words, uses in the UK may continue provided new UK AfAs will be filed within 18 months of the UK's exit from the EU.

Question 4: 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: Yes, unless there are suitable alternatives, they will do so. The organization of this work, however, may differ between suppliers. DUs should consult their suppliers in time for the review report.

¹ See UK HSE advice here (last retrieved September 18, 2019) <https://www.hse.gov.uk/brexit/scenario4.htm>

² <http://www.legislation.gov.uk/ukSI/2019/1144/made>

Question 5: What impact do the authorization decisions have for DUs?

Response: DUs 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 AfAs (see the chemical safety report) and the authorization decisions, and the conditions of the decisions are complied with (see also [Annex 1](#) hereto).

Question 6: What immediate steps do DUs have to take now?

Response: Once the authorization Decisions will have been issued, as a next immediate step, DUs must notify their uses of the substances to the European Chemicals Agency (ECHA) under Article 66 REACH within three months of the first supply of a substance (with an authorization number). This should be, as a rule of thumb, three months after publication of the authorization Decisions (see ECHA and Commission websites and EU Official Journal whatever is earlier). Thus, the Art. 66 notification will likely be due in January 2020 latest for the authorization Decisions issued in October (exact date to be determined). DUs who do not comply with this obligation, might be imposed a fine by their national enforcement authority and/or the national authority may ask them to stop the use of chromates until they have filed the Article 66 notification with ECHA. Please see chart below on actions and timelines.

| Date ³ | Action |
|-------------------|---|
| October 31, 2019 | Authorization Decisions ⁴ notified to applicants (date estimated). Authorization Decisions made publicly available (date estimated) |
| January 31, 2020 | DUs are asked to scrutinize and implement the new specific exposure scenarios for representative processes, operations and individual tasks drawn up and supplied by suppliers together with the template for exposure and environmental monitoring (as annexes to safety data sheets). |
| January 31, 2020 | DUs to notify uses and explanation of the key functionalities and a justification for the necessity of the key functionalities to ECHA under Article 66 REACH |
| April 30, 2020 | DUs to conduct first workers exposure measurement campaigns according to the monitoring template made available by the suppliers |
| April 30, 2020 | DUs to implement monitoring programs for Chromium (VI) emissions to wastewater and air from LEV |
| October 31, 2020 | DUs 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 7: How will a DU know whether the substances he uses originate (were supplied directly or indirectly by) from one or more of the CCST authorization holders?

Response: The labels and safety data sheets of the substances/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

³ All dates are estimated. Final dates depend on date of notification/publication of authorization decisions, as the case may be.

⁴ Except Pentazine chromate octahydroxide.

distributors or formulators supply the substances in mixtures or they have several suppliers for the same substance, 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 chromate substances from a supplier whose application is still pending), as they will critically need those numbers for their Article 66 ECHA notification.

Question 8: Which authorization number should the DU notify to ECHA in case he uses up a substance 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 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.

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 authorization Decisions, that he complies with them including that he applies as a minimum the operational conditions and risk management measures described in the AfAs 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.

ANNEX 1

Note for Downstream Users on Article 66 REACH notifications

September 23, 2019

CCST Consortium

If you are a downstream user ('DU') of miscellaneous chromates delivered directly or indirectly (e.g. through a formulator or distributor) from any of the CCST 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 Decisions, thus at the latest on or around January 31, 2020. 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 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.
- ✓ A brief explanation of key functionalities required for the DU's use (see the key functionalities per substance in the texts of the authorization Decisions) and the related justification (why the key functionalities are necessary).
- ✓ 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 **have to conduct annual workers exposure and environmental (air emissions and wastewater) 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 **October 31, 2020**. Please note that the authorization holders are obliged to issue a reporting format for exposure monitoring (both workers and environment i.e. emissions to air and wastewater) **by January 31, 2020 (estimated date)**. DUs should use this monitoring template for compliance with the authorization Decisions' monitoring requirements. CCST recommend not to submit monitoring data under the Article 66 notification in the initial (January 31, 2020) Article 66 notification but only later, when the new monitoring format will be available and the DUs have conducted

their first measurement campaigns (which must be conducted April 30, 2020)⁵. 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 (e.g. the information on key functionalities and justification). 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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⁵ Estimated date – 6 months after publication of authorization decisions.