ECHA
EUROPEAN CHEMICALS AGENCY

Applications for authorisation of Cr(VI) in electroplating: Web-based information session

15 February 2023*)

15h00 – 17h00 (CET)

WebEx

*) Slide 26 updated on 23 March 2023

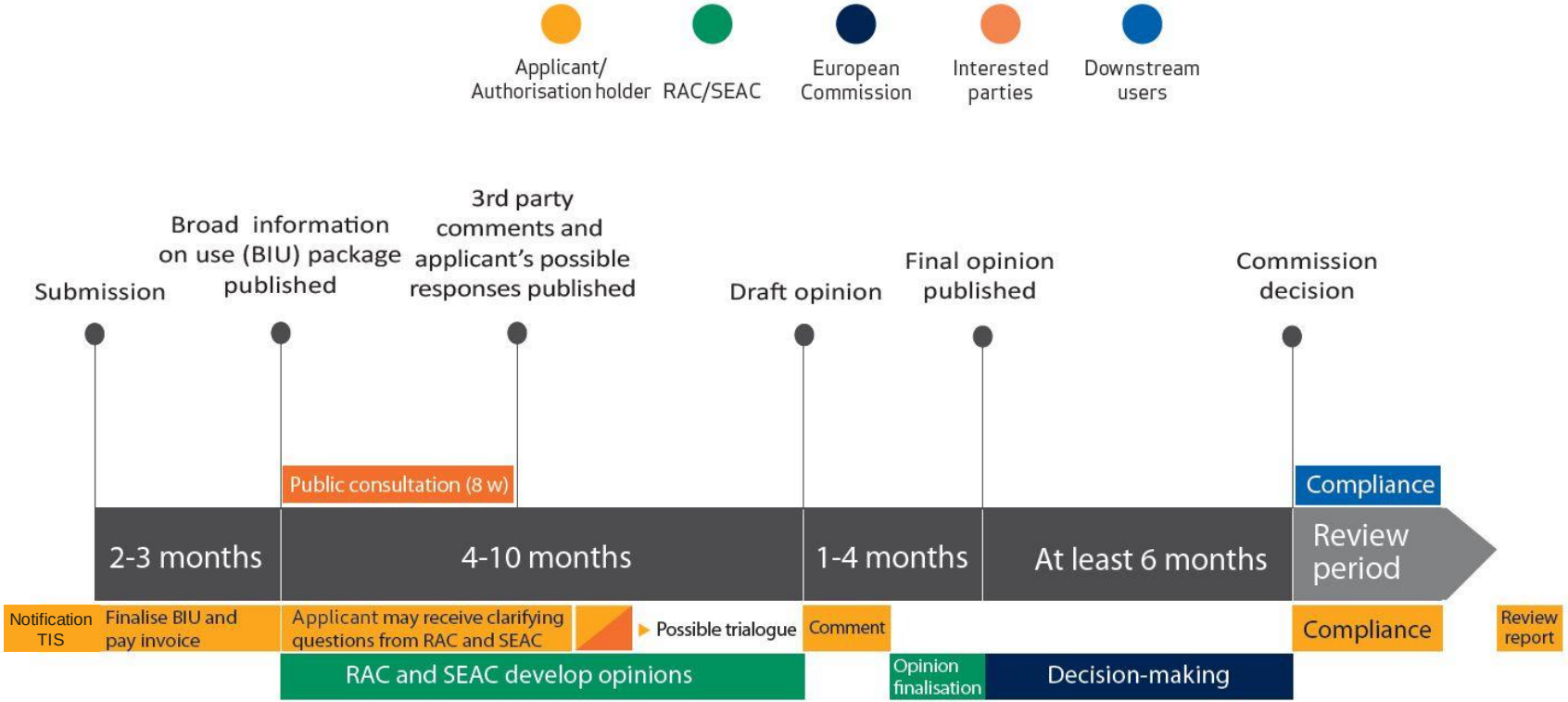
Welcome

- → **Purpose**: Gain understanding of specific technical, procedural and regulatory issues when preparing and submitting an application for authorisation
- → 260 participants, 60 (partly overlapping) questions
- → One joint session instead of individual ones
- → We provide also generic advice
- → Q&A slides are detailed and will be shared on ECHA website
- → Conclusions will also be shared

Agenda

- → Opening *Matti Vainio (ECHA)*
- → Generic advice to applicants *Thierry Nicot (ECHA)*
  - Questions for clarification
- → Responses to questions, Riccardo Zorgno *(European Commission)*
  - Questions for clarification
- → Responses to questions, *Pablo Regil (ECHA)*
  - Questions for clarification
- → Discussion *Hugo Waeterschoot (Eurometaux) & Matthias Enseling (HAPOC)*
- → Conclusions

Timeline of the AfA process



Comments on timelines

→ ECHA usually manages draft opinions in 7 months from start of consultation
- Currently, final opinion in about 13 months from submission

→ Commission's decision making time varies
- Depends also on the views of Member States

→ Current capacity of RAC and SEAC is 60 AfA opinions a year

→ If applications of >15 uses submitted in a quarter, those applied before LAD (or review date) are postponed
- Applicants/authorisation holders informed
- Postponement foreseen for 3-9 months
- Aim is to minimise the disruption of EU market

General recommendations

→ **Notify** ECHA of your intention to submit
- Helps ECHA and committees to get organised

→ Read Q&As, instructions in the formats, recent opinions & decisions

→ Be **transparent**: avoid using of confidential information in the application
- if confidential information is needed, provide always a public version
- this is valid for both quantitative and qualitative type of information

→ **Downstream users**: participate in public consultations on upstream applications & review reports
- Provide information on possible alternatives or their absence

→ **If SME**: Provide all necessary documentation in REACH-IT when you submit your AfA. SME check is performed *ex ante*, surprises!

Generic advice to applicants
Thierry Nicot (ECHA)

General Description of workplace (RAC) (1/2)

→ Detailed description of the workspace/production line, including e.g.:

- number of (plating) lines
- number of Cr(VI) containing baths
- size of the baths
- loading/unloading areas segregation i.e. distance to plating lines, physical separation etc.

General Description of workplace (RAC) (2/2)

→ Transparent and detailed description of the (plating) process:

→ Automation

- if semi-automated indicate the operations which are automated and those which require manual intervention from operators

→ Enclosure/confinement of plating lines

→ Coverage of the baths: full/partial, especially during plating activities

→ Temperature of baths, duration and frequency of plating

- if exact figures claimed confidential provide representative ranges

Ventilation

→ Local Exhaust ventilation (LEV): Efficiency, flow rate, equipped with alarm and shutdown system etc.

→ General ventilation: mechanical or natural. Number of changes per hour

→ Maintenance of Cr(VI) abatement systems, including LEV, scrubbers etc.

Exposure Assessment

→ Monitoring dataset for workers' exposure (Cr(VI) measurements in air at the workplace). Consider its representativeness, provide details such as LoD/LoQ, analytical method used, number of measurements per WCS, personal/static, sampling duration, etc.

→ Realistic calculation of exposure, i.e. duration, frequency of tasks, number of workers exposed, etc should be representative of a working day. **Avoid (over) conservative, unrealistic approach and assumptions**.

OCs/RMMs Improvements

→ Justifications on whether it is feasible or not, including an estimation of the costs:

- to move from solid to **liquid** solution of CrO3
- to **automate bath dosing** system (liquid CrO_3)
- to **automate/enclose sampling** of the bath

And also

- to **segregate** e.g. the plating line from loading/unloading area
- to **cover baths**
- to **automate** the plating line

Other elements to consider

→ Detailed information on RPE including whether fit-check is carried out. Avoid over-reliance on RPE as a way to control exposure (e.g. don't rely on workers wearing RPE for long periods of time)

→ Detailed description of rare maintenance activities i.e. how they are carried out, how worker exposure is minimised (OCs/RMMs, PPE), representative exposure measurements, duration and frequency of tasks

→ Be clear about the tonnage indicated in your CSR

- always express it in Cr(VI) (and not only in CrO_3) e.g. to cover a possible switch from solid CrO_3 to liquid CrO_3 solution during the review period,
- anticipate possible tonnage increase e.g. to adapt to market demand over time

SEA, AoA and SP (SEAC)

→ Include in the application the excel files with calculations for:

- excess risks (ERs)
- monetised risks
- economic impacts of the Non-Use Scenario

SEA, AoA and SP (SEAC)

→ If you are applying for different uses based on *alternatives-driven approach,* ensure that this is also reflected in the AoAs/SPs

- For instance, it is expected that different functional requirements will be described under each AoA and that the uses will have different substitution profiles.
- The scope of the use applied for should be defined in a way as to enable a meaningful assessment of alternatives e.g. not covering sub-uses with different technical requirements and different substitution profiles

→ Make sure to describe the key requirements/performances to be fulfilled by products manufactured with an alternative, including the justifications: e.g. statements that alternatives need to provide same performance as Cr(VI) are not sufficient. Make sure to justify why a specific performance is required - in connection with customers' and/or regulatory requirements - and explain whether a lower performance level is acceptable or not

→ Make sure that the substitution plan is sufficiently detailed and the length of each phase duly justified

Responses to questions
Riccardo Zorgno
(European Commission)

Effects of judgment of the case C-144/21

- → Advocate General opinion supports the EU Parliament in the annulment of the decision.
- → If the Court annuls the decision, it is expected to keep the effect of that decision (including for submitting the review report) until a new decision is taken.
  - In that case, no immediate practical consequences, COM would need to prepare a new decision (likely a refusal) and discuss it within the REACH Committee (i.e. the whole process may take up to one year).
- → To be established in accordance with the judgment whether the new decision needs to be taken on the basis of the 'old' application or on the submitted review report.

Effect of a potential refusal of CTAC use 3

- → Applicant and downstream users need to cease the use if not covered by another authorisation
- → Not possible to set out transitional arrangements in the decision of refusal as not foreseen in REACH
- → Companies not covered by other authorisations need to submit their AfA and wait until a decision is taken on their application
- → Timeline: draft decision to be discussed at the REACH Committee of June – uncertainty on a qualified majority supporting the draft

Backlog linked to big wave of Cr(VI) AfAs

- → COM's assessment of opinions for AfAs had been facing a significant backlog since several years (e.g. more than 100 OPE/NPE applications).
- → COM is aware of the impact of the new Cr(VI) wave of AfAs and is investigating possible ways forward, together with ECHA.
- → For Cr(VI) substances, additional delays caused by difficult discussions at the REACH Committee on functional chrome plating with decorative character (e.g. some drafts discussed multiple times and still without support by the required majority of Member States).
- → Experience: good applications have passed more smoothly than others

Key elements for a smoother decision-making process

- → The speed of approval will to a large extent depend on the quality of the application
- → Clear scope of the use applied for → clearly identifying the use and enable a meaningful assessment of alternatives e.g. not covering sub-uses with different technical requirements
- → Robustness of the analysis of the availability of alternatives
- → Robustness of exposure/emission data
- → Minimisation of the risk – exposure/emission values as low as technically and practically possible

Definition of the review period

→ Elements to be taken into account for defining the length of the review period (Article 60(8) REACH):

- the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
- the socio-economic benefits arising from its use and the socio-economic implications of a refusal;
- the analysis of the alternatives or any substitution plan, and any third party contributions;
- available information on the risks to human health or the environment of any alternative substances or technologies.

→ COM has the right to deviate from the RAC/SEAC recommendation, based on its own assessment, and duly justify it.

→ COM does not involve or consult the applicants in this stage of the decision making. For the sake of transparency the drafts are made available in the comitology register ahead of each REACH Committee meeting.

→ Length of the review period is often questioned by Member States, important to well justify the substitution steps.

Responses to questions
Pablo Regil (ECHA)

1. Grouping and fast-tracking of similar AfAs to shorten time for opinion processing

We understand applicants' concerns regarding the timing for obtaining an authorisation for their use.

Both ECHA and the European Commission are aware of the issue. ECHA is doing its best to organise the work in such a way that this peak of applications can be dealt with in a fair, orderly and effective way.

Current capacity of RAC & SEAC is 60 opinions per year, i.e. 15 per quarter.

If above this, ECHA postpones the start of the opinion making.

ECHA aims to deliver draft opinions in 7 months from the start of the consultation

Each AfA must be evaluated on his own merit. ECHA tries to find synergies by assigning same rapporteurs and same ECHA staff for similar cases

2. Downstream user currently relying on the authorisation granted to Chemservice GmbH and others and others for functional chrome plating ('CTAC use 2') until 21 September 2024. What can the applicant do to extend the authorisation beyond this?

DUs must:

→ be covered by a **review report** submitted by their upstream actor(s) (i.e. original authorisation holder(s)) in this case, Chemservice GmbH and others at least **18 months before the expiry date** of the review period of this authorisation, in which case transitional arrangements under Article 58(1)(c)(ii) of REACH (allowing continued use of the substance) apply until the European Commission's decision is issued, check Q&A 1361-1362

and/or

→ submit a **new authorisation application** for their own use (and, if relevant, downstream uses) well before the authorisation granted to their upstream actor(s) expires, and get granted an authorisation for this use.

3. What happens if the applicant submits their own authorisation application for deco-plating and the CTAC Use 3 application for authorisation is refused by the Commission within the processing period for their application? Is the applicant then allowed to produce continuously?

→ It depends on when the Commission makes its decision.
- No transitional period if authorisation is not granted
- Time required for the Commission is not known
- Uncertainty created by this is understood

→ Opinions and decisions are given normally
- Currently, RAC/SEAC agree on the draft opinion in 13 months from date of submission (draft opinion in 7 months from the start of the consultation)

→ Due to the very high number of applications for uses of Cr(VI) substances it will take longer to provide opinions and decisions
- Some applications are staggered and the opinion making is postponed by 3-9 months.
- If applications are made after the latest application date, ECHA tries to start the opinion making without delay.

4. Many companies are relying on CTAC for their upstream authorisation. If, the European Court of Justice (ECJ) annuls the CTAC authorisation, how will it impact this coverage?

→ A possible annulment of the authorisation decision does not immediately prevent companies from continuing to use the substance provided that they adhere to the conditions of the Commission decision and any additional consequences of the judgment

→ They would be allowed to do so until the Commission takes a new authorisation decision.

- The initial authorisation application was submitted before the latest application date (and the transitional arrangements continue to apply)
- This all will become clearer once the ECJ is known

→ A CTACSub2 Review Report is planned to be submitted in February 2023

- It will only cover those DUs that have signed up as well as those who have a valid authorisation*)

→ This RR might be treated as a new application for such cases if the original authorisation is annulled

- RAC and SEAC would then process such "new AfAs" following the timelines and procedure explained earlier

*) Updated on 23 March 2023

5. How can a co-applicant inform ECHA about ceasing or changing of the activities concerned by the authorisation?

→ See Q&A 1807 *"How do I cease all notified uses of a substance for which I have sent a Downstream User notification of authorised uses?"*

6. Typically, AfAs take the maximum volume anticipated into account. How can a potential increase best be communicated in the application, knowing that RAC would prefer a reduction in the usage of Annex XIV substances?

→ Provide a sufficient range in your AfA to allow for the possible increase during the review period. If exceeded during the period, inform National Enforcement Authority

→ See Q&A 1858 on the increase of tonnage within an authorisation

7. Where to get information about possible alternative substances or techniques to Cr(VI)

- AoAs from past AfAs (find them in ECHA's website Adopted opinions and previous consultations on applications for authorisation - ECHA (europa.eu))
- Information online to be explored by the applicant, e.g., like universities, reports from workshops, also SUBSPORT plus portal
- AI based search tools, e.g. IGOR^AI

8. To better delineate the scope of use, can a reference to another EU legislation be made in the use name?

Yes, if it helps to define specifically the use. Make a reference in the use name to the particular additional EU legislation/regulation (ROHS, etc).

9. Niche applications: e.g. use of Cr(VI) for legacy spare parts on historic vehicles. Can this use be covered by a simpler application?

→ Yes, there is a simplified process: Application for legacy spare parts (https://echa.europa.eu/simplified-applications-for-authorisation-for-legacy-spare-parts).

→ The format for the chemical safety report is the same as for other applications for authorisation and review reports. A substitution plan is not required

→ Thus far, no such applications have been submitted.

10. Can SEA take into account the costs for the downstream industries if they are deprived of chrome plating (for surface treatment) from the applicant, so long as it can be shown there is no alternative provider of chrome plating services or alternative surface treatment methods?

→ Yes, SEA can take into account impacts of the non-use scenarios on downstream industries, in particular if these are costs to the society and these are justified and described.

11. If there are many similar applicants (same AoA and SEA) but the exposure scenarios are different would it be possible that RAC opinions would recommend separate conditions for these exposure scenarios (some none, some a lot)? Could SEAC recommended different review periods? Recommendation to apply jointly or separately?

→ Yes, RAC can propose different conditions per Exposure Scenario or per site. These could be site-specific depending on the existing RMMs/OCs and exposure per applicant and per site

→ For joint submission for same use(s), SEAC would recommend one single review period per use

→ ECHA cannot always give a recommendation on whether it is preferable to apply jointly or separately (both have pros and cons).

- For instance a joint submission for the same use would be meaningful in case of applicants with comparable OCs/RMMs and substitution profiles for this use.

→ See detailed information on ECHA's webpage on authorisation, there you can find several specific guidelines e.g. step-by-step guide to applicants, guidance on the preparation of an AfA, etc

https://echa.europa.eu/applying-for-authorisation

12. Joint submission: protection of confidential information

- → Lead Applicant submits the AfA via REACH IT, this submission includes all relevant public info. (i.e. public versions of CSR, AoA/SEA, SP)
- → Webform for the submission of confidential information, this is managed often by a third party (e.g. consultant)
- → Communication (i.e. additional request of infomation from RAC/SEAC) via third party to preserve the confidentiality of questions/answers

13. Can alternatives involving the use of other a SVHCs be considered suitable? What information is needed for RAC to assess whether an alternative is safer?

→ In general, substituting a SVHC with another SVHC (even if it is not in the Annex XIV list) is not recommended (due to risk of regrettable substitution)

- Include such information in the AoA to know what the consequences are if authorisation is not granted.

→ For understanding if an alternative is safer,

- provide a the hazards of the alternative,
- exposure assessment of the alternative
- It is understood that this is not easy

14. Many companies (from the application of CTAC onward) have argued that there is currently no alternative to functional chrome plating. Given this, can they refer to the "state of the art" outlined by previous applications? Or should they try to convince SEAC of this with a new wording of the previous AoA and substitution plan?

→ Companies need to submit their AfA with their own specific AoA
- Remember that the AoA for the original CTAC was prepared many years ago

→ Substitution Plan needs to reflect applicant's and sectors (if known) substitution activities
- actions, tests carried out, phases, timelines for implementation, etc
- be ready to respond to specific questions from SEAC.

→ Each AfA is evaluated on its own merits

15. How does RAC approach situations where there may be concerns with an aspect of an applied-for-use (e.g. relating to current conditions surrounding a use, or exposure from certain parts of processes or individual Worker Contributing Scenarios in the CSR)? What are the Committees likely to do in such a case, e.g., agree on an opinion for authorisation with additional conditions? Are there other possible outcomes?

RAC will conclude on each use whether OCs/RMMs are:

- → Appropriate and effective in limiting the risk (with the possibility of conditions/monitoring arrangements).
- → Not appropriate and effective, (always conditions and/or corresponding monitoring arrangements)

16. Articles treated with Cr(VI) (e.g. Functional chrome Plating) may be applied for defence. Is it possible to ask for exemption in this case? If yes, how it should be requested?

→ Member States may allow for exemptions from REACH in specific cases for certain substances

→ Contact your Member State Competent Authority.

Discussion

Hugo Waeterschoot (Eurometaux) &
Matthias Enseling (HAPOC)

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