

Summary conclusions from the Webinar-workshop of 18 June 2020
“2nd Webinar on Suitable Alternative Generically Available and Substitution Plan for SEA route AfAs of the Chromates sector”

Objectives and background

Eurometaux (the European non-ferrous metals sector) and CETS (the European Committee for Surface Treatment) facilitated 2 workshops, for EU authorisation applicants of CrO₃, their downstream users and contributing consultants, to increase their understanding of the challenges posed by the Commission’s recent letter requesting a Substitution Plan (SP) in follow-up of the General Court case T-837/16. The Commission concluded from this case that if *“Suitable Alternatives are available in general but those alternatives are not technically or economically feasible for the applicant, and it if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, an authorisation may be granted if the applicant submits a Substitution Plan”*.

The first workshop took place on 28 May and aimed at collecting views, progress with the preparation of a Substitution Plan and questions from applicants, downstream users (DUs) and consultants on the SAGA concept, to define the topics for further evaluation and discussion at a second workshop. This follow-up workshop took place on 18th of June.

More than 50 participants attended the second workshop, covering applicants who received the COM letter, downstream users, consultants, facilitators and observers from ECHA and Commission.

Reminder on the outcome of the first workshop and objectives of the second workshop

As stated, the second webinar-workshop aimed at building on the progress and issues for clarification defined during the 1st workshop and in addition to report back on the outcome of the discussions on the SAGA concept at the latest SEAC meeting. The latter took place early June in between the 2 Chromate workshops.

Moreover, since the end of May, Consortia had the opportunity to review and consider the clarification COM provided in their explanatory note on the SAGA concept (published end of May), as well as the update of the guidance template for the Substitution Plan, that ECHA recently made available (see [ECHA’s website](#)).

Eurometaux reminded the webinar participants of the main learning lessons from the 1st workshop, using selected slides from the presentation provided to SEAC on the 2nd of June:

- The SAGA concept remains a difficult and confusing concept:
 - o How to further clarify this?
- The explanatory note of the Commission (dd 27 May) on *Suitable Alternatives Generically Available* offered further explanation but consortia needed more time/interchange to explore the consequences
- Recognition that:
 - o for the SEA route a Substitution Plan would in principle also be needed
 - o the role of the Substitution Plan under this route.
 - o A transparent and clear Substitution Plan would help the decision-making process hence a better outcome of it (e.g. longer review period, less conditions, ...)

- Downstream users are still struggling with the concept and their role in the update under preparation by the applicants
- Understanding by all parties that narrowing down the “use” into “sub-uses or utilisations” would be required. However, how to keep the balance in “narrowing down” and the main goal of “upstream applications” remains unclear.
- *Key technical functionality requirements* of the substance’s use can help in defining the sub-categorisation of the uses

The first workshop defined a list of issues that required further explanation or processes to be clarified as listed in the slide hereunder:

List of issues for further consideration...	
EXPLANATION • Terminology: uses/utilisations/process steps • “Generically” applicable vs “specifically” • The role of (performance) Technical standards • A Toll player has no control on the substance • DU’s drive innovation but applicants are usually more upstream • How to deal with “advancing knowledge”	PROCESSES: • Involvement of users by upstream applicants • Transparency of the applicants about what they are aiming for • Some alignment between applicants on approaches (SAGA, Suitable alternative, ...) • BUT also with other substances

SEAC

At the SEAC meeting in June, the Commission (DG Grow) gave a presentation on their main conclusions on the outcome of the Court Case (T-837/16) in respect to the Substitution Plan and a report from Eurometaux on the 1st Chromates SAGA workshop.

The participants of the webinar were in short informed by ECHA that SEAC:

- appreciated Eurometaux’s status updates on the discussions within industry, as well as the Commission’s clarifications on the SAGA concept
- remains unclear on *how substitution plans under the SAGA concept* will have to be assessed
- looks forward for further information including the outcome of 2nd workshop of Cr(VI) in surface treatment scheduled by industry on 18 June

ECHA further briefed the webinar on how the ECHA secretariat expects the Substitution plans to be received and processed by SEAC. From a process viewpoint ECHA will:

- Place the public part of the Substitution plan (and related supplementary information) on the ECHA website as soon as they receive it from the applicants
- Allow for possible comments from third parties and responses to the comments of the applicants on the third parties’ suggestions
- Different than for applications, no further interaction will be foreseen between SEAC, the Rapporteurs of ECHA and the applicants (so no dialogue, nor additional questions for clarification)
- SEAC will publish its conclusions under the form of an addendum to the original opinion, possibility allowing the applicant to comment on the draft addendum

Content wise SEAC will focus on:

- Assessing the submitted substitution plan as such with emphasis on the substitution timeline, as suggested by the applicant
- Commenting the timeline at the level of “utilisations” or “groups of utilisations” (or other sub-divisions)
- Following the criteria set in the General Court’s judgment and documented in the instructions of the updated format for Substitution Plan (see ECHA website 1 June 2020)
- Carrying out a technical evaluation of the argumentation for no SAGA, in case no Substitution Plan is included

ECHA expects to receive the first Substitution Plans in follow-up of the COM letters, on 24 August (CTAC) while the last one may arrive around the end of the year (by Plastic Planet, tbc). ECHA will try to assess similar sub-applications in batches which would facilitate consistency. In respect to further timing, ECHA has scheduled:

- Posting the public version of the first submission (CTAC) on the website, by the end of August
- Holding an “orientation discussion” on the first submission of Substitution plans at the SEAC meeting in September
- Starting the content assessment of the first Substitution Plans, in December
- Completing the assessments by June ‘21, although that depends on the submission dates

Eurometaux further complemented the background briefing with the main messages of the Commission’s learnings from the outcome of the Court Case (T-837/16), as presented to SEAC:

- A reconfirmation that also for the SEA route a Substitution Plan may be needed



- whereby the main issue introduced by the General Court is the question on “whether there are suitable alternatives available in general”?.
- the main criteria to identify suitable alternatives:



In conclusion, the discussions at SEAC level were rather exploratory, confirming the lack of clarity on the concept. Important is that all parties realise the need for finding a reasonable balance between the number of “sub-utilisations” and the “specificity of the Substitution Plans”. So far it seems impossible for SEAC to indicate some generic recommendations meaning that the learning will be on a case by case basis. SEAC reconfirmed its interest to remain informed on how industry is progressing with the application of the concept and more specifically the sub-division of uses as a function of the potential for substitution.

Questions from the participants of the webinar on the ECHA and Eurometaux presentations:

- ECHA confirmed that the posting of the Public Version of the first SP submission on ECHA's webpage, would provide an indication to other applicants of what utilisations CTAC had identified. However, this would not mean that ECHA or SEAC would not accept any other sub-division! *Indeed, every substitution plan would be evaluated on its own merit. However, given that the focus is on Substitution it would be up to the applicant to prove why he considered that a generically available substitute (e.g. Cr3+ plating) would not be applicable to him/her*
- Would there be no dialogue on the SPs submitted? *Indeed, no further interaction on the submitted Substitution Plan is foreseen, beyond the Public Consultation in the beginning.*
- Would the court case conclusion on the need for a Substitution Plan under the SEA route be applicable for future authorisation applications too, including the SAGA concept? *Yes!*
- Would COM or ECHA consider a formal definition of “utilisation”? *No!*
- Would the court case outcome mean that an applicant needs to keep its SP updated after submission? *An applicant would normally always keep track of new substances / technologies as part of the Substitution Plan obligations.*

Panel debate on outstanding questions and concerns as identified at the 1st workshop

Four panel members were invited to provide opinions on 3 pre-identified questions that should help attendees, but also SEAC and Commission to better understand how the SP dossiers may develop:

- Applicant: Matthias Enseling (Veeco):
- Applicant: Martine Vosteen (German plastic platers, by Ramboll)
- Applicant for a reauthorisation Consortium: Meg Postle (RPA) (for ADCR)
- Upstream applicant for another substance: Bernadette Quinn (REACHLaw)

It was reiterated by the organisers that *the ideas and comments raised by the Panel members in response to the questions are based on their expertise and experience and are not (necessarily) a position/proposal of the Consortium they represent.*

Q.1. To what extent do you see it possible, in your case, to further split the concerned “use” (e.g. functional plating with decorative character) into “sub-uses” (functional utilisations) in balance with differences in substitution options/possibilities?

- The split in utilisations cannot go as far up as the component level. So, a balanced approach will be needed, given that for the chrome platers for example there are approximately 6000 components that are functionally plated.
- An applicant used a grouping approach based on *key functionalities* to define about 15 clusters. Interaction with the DUs on those clusters could hopefully further reduce the number

- Another applicant representative indicated that besides key functionalities “technical standards” and “certifications requirements” will also determine if -especially- toll platers can use a substitute or not. Additionally, applying the same plating technique on different materials (metals) may already change the conditions for finding a suitable substitute. So, the real question is *“how to simplify the way to find an “attractive number of utilisations to develop an SP for (or demonstrate it isn’t needed) without overwhelming everybody, while ensuring a convincing case for SEAC”*
- Another applicant used a more theoretical approach to define a best way to divide the use in different sub-uses. The main challenge remains that the splitting must be practical (e.g. by technology: plating, etching, ...). This seems a reasonable way forward but will still require demonstrating feasibility
- The issue of splitting uses is equally valid for other substance-consortia that received a comparable letter. They also struggle with the balance between splitting into sub-uses and the specificity of a SP by product use. The panel member indicated that in their case the balance between splitting and communalities is based upon process characteristics, specificities of product types and the need for different Review Periods based on substitution potential

Comments from the participants:

- o a relevant splitting may also benefit the applicants given the Substitution Action Plan and timing can be better defined which may result in a better review period
- o in some cases, an “alternative-driven approach” to split the use may be the solution, especially when several alternatives for different parts of the use would be feasible
- o many of the chromate applications are old and since then guidance evolved. It could therefore be good to provide some direction on what an appropriate “utilisation” vs “use” is, to prevent a mismatch occurring again
- o others stated that the term “utilisation” has no real meaning other than splitting the originally submitted use (e.g. use 3 on functional plating with decorative character).

Overall recommendation from the panel: the specific key functionalities, use processes, feasible alternatives and needs for differentiation in Review Periods, may be logic arguments / criteria to define an appropriate split for the use of Cr6+ on plating with decorative character

Q2. Do you see merit in cooperation/exchange with other Authorisation consortia to align on splitting, scoping or boundaries of the “functional utilisations” for a use?

- While each (re)application will be different it makes sense to exchange experience to promote findings that balance between splitting and communalities. While this is first a task for the applicant-consortium, DUs may be of help in stimulating alignment on the sub-uses
- Some CTAC members replied that they expect the applicants’ consortium will use the outcome of the questionnaire (> 900 replies) to define the sub-uses, hence finding some alignment between the views of DUs that contributed
- Another applicant confirmed the relevance of some form of cooperation or exchange to define: *some common ground on the level of detail required for the SP, some interchange on common “sub-uses”*; but insisted that such alignment should be discussed directly with the users
- The latter comment inspired the statement that *“the split should preferably be described from the user’s point of view rather than from the perspective of the upstream applicant”*.

- Alignment on the split of uses should be promoted but another applicant indicated that in the end *not only the technical* but also the *economic feasibility* would determine the “suitability” of the SP and requested Review Period
- A representative of a DU indicated that in many cases the letter may drive individual user companies to apply separately in case the proposed Substitution Plans do not fit his/her situation exactly, for technical (e.g. standards) or economic reasons
- A user representative indicated that even for the Substitution Plan there could be communalities (e.g. replacement by Cr3+ plating), but that the timing required to reach this alternative solution could be different for different users for reasons of technical and economic feasibility. So, a search for alignment on the SP or aspects of it, should not be negated

Overall recommendation from the panel: a strive for alignment of the level of split into sub-uses is certainly recommended based on the potential for substitution. However, there should be recognition that technical standards and economic feasibility may impact the suitability for specific users

Q.3. What are your expectations from SEAC, in respect to the review of the split in “functional utilisations” and “specific Substitution Plans”?

- Applicants expect a recognition that the split in different “sub-uses” could lead to different review period recommendations. Each sub-use should consequently be assessed separately
- ECHA indicated that SEAC will only be asked to evaluate the content, quality and plausibility of the SP and document this in the addendum; thereby indicating that it is COM who decides on the Review Period
- Several applicants indicated that splitting the use into sub-uses depending on the potential for substitution as well as an assessment of the associated uncertainty, should allow revising the original Review Period
- Applicants expect SEAC to review the relevancy of the split of the use in utilisations. It would be most relevant to ensure an interactive learning process in one or another way given SEAC already indicated this will be a “learning by doing process”.
- Several consortia used the wording “R&D planning” for a SP under the SEA route given the REACH text foresees that an SP relates exclusively to the adequate control route. It was asked that SEAC should recognise this difference
- Recognition by SEAC that the SP / R&D plans may have changed significantly since they were originally submitted (if included) given the technical knowledge and science developed over the last 5 years
- Would the Commission consider different Review Periods for different utilisations if the SP (including the actions and timing) warrants such differentiation?
- Some applicants commented on/criticised the short time provided to them to submit a SAGA or specific Substitution Plans given the technicality of the question and the difficulty these days to interact with users. The 6 months provided was seen as not being in balance with the long period the political debate took.
- The facilitators indicated in this respect that one applicant had asked for a prolongation based on the challenges Covid-19 posed to interact with the users. The applicant got 2 months additional time granted from COM.
- ECHA reconfirmed that neither the SEAC committee nor the SEAC rapporteurs will ask for further clarification once the SP is submitted. The review by SEAC of the SP is clearly different to the review of a new Application for Authorisation (AfA).

Conclusions and potential next steps

The workshop's conclusions on the 3 questions were summarised by the facilitators as follows:

- There remains some confusion on “how” and “how far” the detail should go in defining sub-uses or so-called utilisations for the use of Cr⁶⁺ for the plating with decorative character, but also in the case of the other substances that received such Commission letters
- A combination of key technical functionalities, process and product type specifications and the time needed to substitute (or not) (so the review period), seem the most indicative criteria to define the balance between “splitting the use” and the “specificity of the Substitution Plan”
- The downstream users have the knowledge to split uses accordingly, but there remains uncertainty on the achievability of the Substitution Plan and the way that SEAC will handle this
- There seems to be some willingness to collaborate (or at least on the principle need for) on how this use can be split while there is recognition that the situation for the individual plater may be somewhat different due to technical or economic considerations
- Recognition that this will be “a learning by doing process”. Posting the public part of the first submitted Substitution Plan as soon as feasible on ECHA's website for consultation may help / stimulate further alignment in the same, or a different direction
- SEAC is invited to recognise the split in utilisations based upon the balance between further splitting and detail of the Substitution Plan for an upstream application
- The applicants, DUs and sectorial organisations regretted the decision coming from ECHA's secretariat to exclude any interaction once applicants have submitted the Substitution Plan given the expected “learning by doing process”, for each of the parties involved
- Finally, SEAC and the Commission are invited to consider the requests for a differentiation in the review periods for different sub-uses/utilisations recognising the technical and economic feasibility of the alternatives and the remaining uncertainty

While no formal **next steps** beyond this second webinar were foreseen it was proposed to:

- Report the outcome of this second workshop to SEAC at its September meeting, including the outstanding difficulties and questions for the applicants and DUs
- Industry sector organisations would report back on the reaction and outcome of the discussions by SEAC as well as the main learnings from the scheduled “orientation debate” at SEAC
- The Commission representative indicated that he noted the questions for the Commission and will check “if” and “how” an answer can be provided
- As indicated after the first workshop, the industry facilitators will set up a blog for applicants and downstream users to promote interpretation, to provide further context and to encourage the learning potential and a possible alignment of the sub-uses when relevant

The slides used for the introduction of this second webinar are enclosed.

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