Silver strategy

1. Introduction

Silver is atypical in the PMs, as being high tonnage coupled with multiple uses involving the general public. Silver is currently under high regulatory pressure mainly due to its environmental classification, its nanoforms and its biocidal uses. The latter is particularly concerning since - during the CLH (harmonised classification and labelling) process under the Biocidal Product Regulation (BPR) - a classification as reprotox cat 2 has been agreed for silver zinc zeolite and is under discussion for some other silver containing active substances (SCAS). This classification is mainly attributed to the silver ion. So far, the industry has been able to avoid a reprotox classification for silver and its compounds registered under REACH. However, a scientific data gap related to reprotox of silver has been identified by PMC and was addressed in 2015 by submitting a testing proposal (TP) for an EOGRTs (Extended One Generation Reproductive Toxicity study) in the metallic silver REACH dossier. The proposed test article in the TP is silver acetate, and testing outcomes of this study are anticipated to be fully applicable to ionic silver irrespective of the donor silver substance forming this ion (i.e. to metallic silver and all silver compounds registered under REACH). Since 2015, further research has been published suggesting silver may be reprotoxic (maybe even cat 1B, which would have severe consequences like restriction of silver for consumer use and silver being banned in the EU from certain electronics, silverware, medical devices, biocidal use, etc.). PMC has identified several weaknesses in the recent silver research and is of the opinion that the data gap still remains, but an update of the TP is necessary.

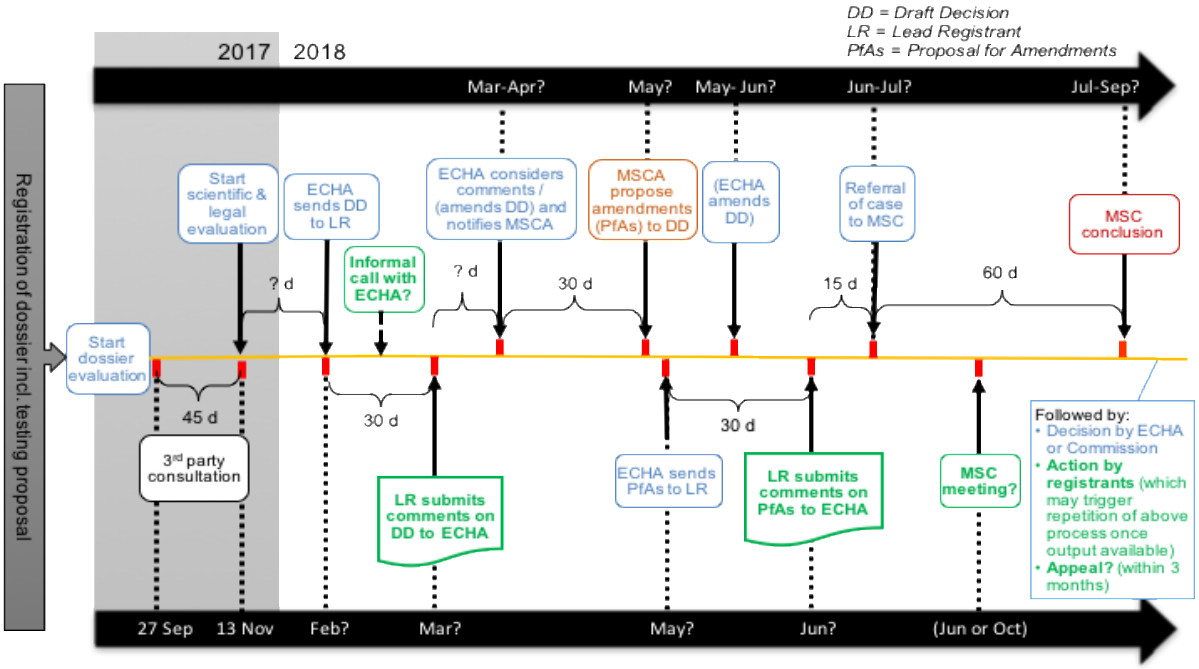
The TP is now under scrutiny by ECHA and is a critical milestone in the discussion on the potential reprotox classification of silver, without guaranteeing of course a non-classification. Indeed, the outcome of the study is very unpredictable but is essential to have a sound science based (non-)classification in the future. It is therefore essential from one hand to defend the TP and the need to conduct the study before continuing the discussion on a silver reprotox (non-)classification. On the other hand, it is also important to map at this stage the classification risks, their impact on the business and their mitigation. For both, a strong and clear advocacy must be developed.

The aim of this document is to outline the silver advocacy strategy given the recent recognition of silver as a possible reproductive hazard escalates the already delicate situation regarding Ag regulatory risk.

2. How to defend the TP on EOGRTs?

Several aspects must be taken into account for the defence of the EOGRT TP: the actions to be conducted, the timing and stakeholders to involve.

First, we need to consider the process and the different opportunities to influence. Please note that the below timing is tentative and is the worst-case scenario:



In the TP process, there are 4 opportunities to interact and defend the proposal (green text in above scheme):

1) An informal call with ECHA after receiving the draft decision;
2) The written comments on the draft decision;
3) The written comments on Proposal for Amendments (PfAs) by MSCA (if any);
4) A discussion at the MSC meeting (if the written approval route is not chosen).

When the final decision is available, there is also a time window of 3 months to introduce an appeal.

The timing for receiving the draft decision being still unclear but the time to comment being very short, it is essential to be well prepared. The immediate actions are:

- Review the EOGRTs TP in light of the recent publications in the literature, and develop the best possible science rationale for why it would provide a superior end result to hazard assessment;
- Ensure that a strong justification is available for the source substance and the read-across approach chosen;
- Prepare the defence of the TP by consulting the relevant experts and gathering their input to support the need to perform the EOGRTs;
- Gather the justifications to perform enabling studies and document the impact on the timing of the overall testing program.

This preparatory work will be the basis for commenting the ECHA draft decision and the starting point for an informal discussion with them.

The next actions will depend on the likelihood to have the TP accepted or not.

- If after discussion with ECHA, we do not identify any major concerns related to the acceptance of the TP, we will need to focus mainly on the acceptance of the study design and timing. The latter will be the most critical since the details of the design can still be refined after receiving the final decision with proper justification. It will also be important during this process to monitor

the reaction of the MS (Member States) and the first insights will only be known via the PfAs (if any). If there is no agreement between MS and ECHA, the issue will be discussed by the MSC (Member State Committee). However, if there is an agreement, the final decision could be finalized by written procedure. If this final decision is not taking the direction that we want, we will need to trigger a discussion at MSC to have another chance to expose our views. However, this cannot be done contacting directly MSC representatives but only CARACAL members or ECHA secretariat via Eurometaux.

The detailed strategy will have to be built step by step depending on the outcome of each step of the process.

- If the testing is refused or if the requirements are not considered as reasonable or in line with the needs identified by the PMC Tox Experts, the last resort will be to appeal against the final decision and this must be done within 3 months after receipt of the final decision. However, as for the Substance Evaluation, this is not considered as a preferred option and all the efforts must be put upfront in the process.

In parallel to the development of the scientific arguments, it will be important also to develop a broader advocacy plan in preparation of the next steps of the process. The following actions are foreseen:

- Development of the mass flow analysis of silver;
- Summary sheet on the socio-economic importance of silver;
- Stakeholders mapping including a DUs (Downstream Users) mapping;
- A DUs communication plan including key messages on the process.

Regarding the stakeholders, it is already obvious that Sweden (Kemi) should be contacted rather quickly in the process since they are the rapporteur MS (RMS) for the SCAS under the BPR and as such, in charge of the CLH proposals for these substances (including a CLH proposal for elemental silver). This could be a follow-up meeting of the meeting with Kemi organized in January 2017 and this could become instrumental to align the different timings but also to defend already the need for additional data before concluding on the classification of elemental silver. The timing for this meeting should be carefully assessed but probably not decided before receiving the draft decision on the TP from ECHA. In this context, the communication with ESTF (European BPR Silver Task Force) will be critical and the relationship or collaboration in this field must be carefully assessed to avoid any counterproductive effect.

3. Reprotox classification: how to conclude?

In respect of the classification process for reprotoxic effects, differing scenarios are foreseeable:

3.1. EOGRTs is rejected

If the testing is rejected, it is almost inevitable that silver will be classified for reprotox on the basis of the existing studies (and there is an appreciable risk that classification will be as high as cat 1B). Therefore, it will be important to consider the development of data which could trigger different interpretations and/or conclusions (e.g. still conducting the enabling studies foreseen in the context of the existing TP to support the PMC hypothesis that the silver mode of action for reproductive effects includes indirect effects and/or that the mode of action is of no/limited relevance to humans). These studies can be conducted without a TP and could clarify the interpretation of the existing studies. Of

course, the different options regarding classifications remain and could be comparable to the one listed under 3.2. (no classification / Repr cat 2 / Repr cat 1B) and therefore, could trigger similar actions.

3.2. EOGRTs is accepted (with modifications)

Before envisaging the conclusions of the study, it is important to ensure that the CLH process under the BPR will take the ongoing TP process into account. It is critical that no harmonized classification is agreed before having the outcome of the testing which could take until 2020. Changing an existing classification is very difficult especially when this is a declassification since a MS must accept to take the lead in this process.

3.2.1. The study outcome is clear: no classification

Ensure that the results are properly integrated in the registration dossier(s) but also are taken into account by Sweden in the CLH process for the pending SCAS decisions, especially for simple silver forms (silver and silver nitrate).

3.2.2. The study outcome is unclear and leads to divergent scientific views

If the outcome is unclear, there is an appreciable risk that the MS/ECHA push for a classification as reprotox cat 1B for precautionary reasons. However, this could also lead to a classification as reprotox cat 2 if the evidence is not sufficiently convincing to assign cat 1. The regulatory consequences of a cat 2 classification are less severe than a classification as cat 1B (and due to REACH testing, a cat 2 classification is becoming increasingly common and is less stigmatising to a substance). At this stage, this is very difficult to predict since the number of unknown parameters is far too high. However, also in this case, further data on the mode of action and the relevance to humans (see also point 3.1) will be important to avoid a cat 1B classification.

3.2.3. The study outcome is clear: classification reprotox cat 1B

The registration dossier(s) must be updated accordingly and the CLH under the biocides process too. It is important to understand the regulatory and supply chain consequences of a classification as reprotox cat 1B.

4. Consequences of a classification

4.1. Classification reprotox cat 2

Link to Eurometaux Excel file on regulatory consequences to be included when available

4.2. Classification reprotox cat 1B

Link to Eurometaux Excel file on regulatory consequences to be included when available

5. How to mitigate the impact of a classification?

Some of the downstream consequences are difficult to mitigate. For example, a restriction on consumer use is quasi inevitable for reprotox cat 1B and of course for silver this will have an enormous impact on the silver business (e.g.: jewellery, food contact material etc.). However, some avenues could be considered like bioelution testing as a tool to estimate human exposure during use. It will be also

important for all other uses of silver and silver compounds to develop some shadow RMOAs (Risk Management Option Analysis) and some supporting studies (e.g.: AoA (Assessment of Alternatives) in some sectors) to defend the best risk management measures and ensure that the “easy” route of Authorisation is automatically chosen by the regulators.

6. Conclusions

At this stage of the process, it is very difficult to develop a full strategy related to silver due to the high number of unknown parameters. However, it is clear that a layered defence will be needed, i.e. even if the EOGRTS TP fails, the fall-back of an effective technical defence to mitigate a reprotox cat 1B classification risk should be ready to deploy, along with a further layer of other advocacy actions. This outline is designed to help to prioritize the actions and also understand the importance and long-term consequences of the reprotox discussions. Therefore, this document is a living document and must be updated on a regular basis to reflect the status of the process and related actions needed.