



24 February 2015

Preparatory document No. 4

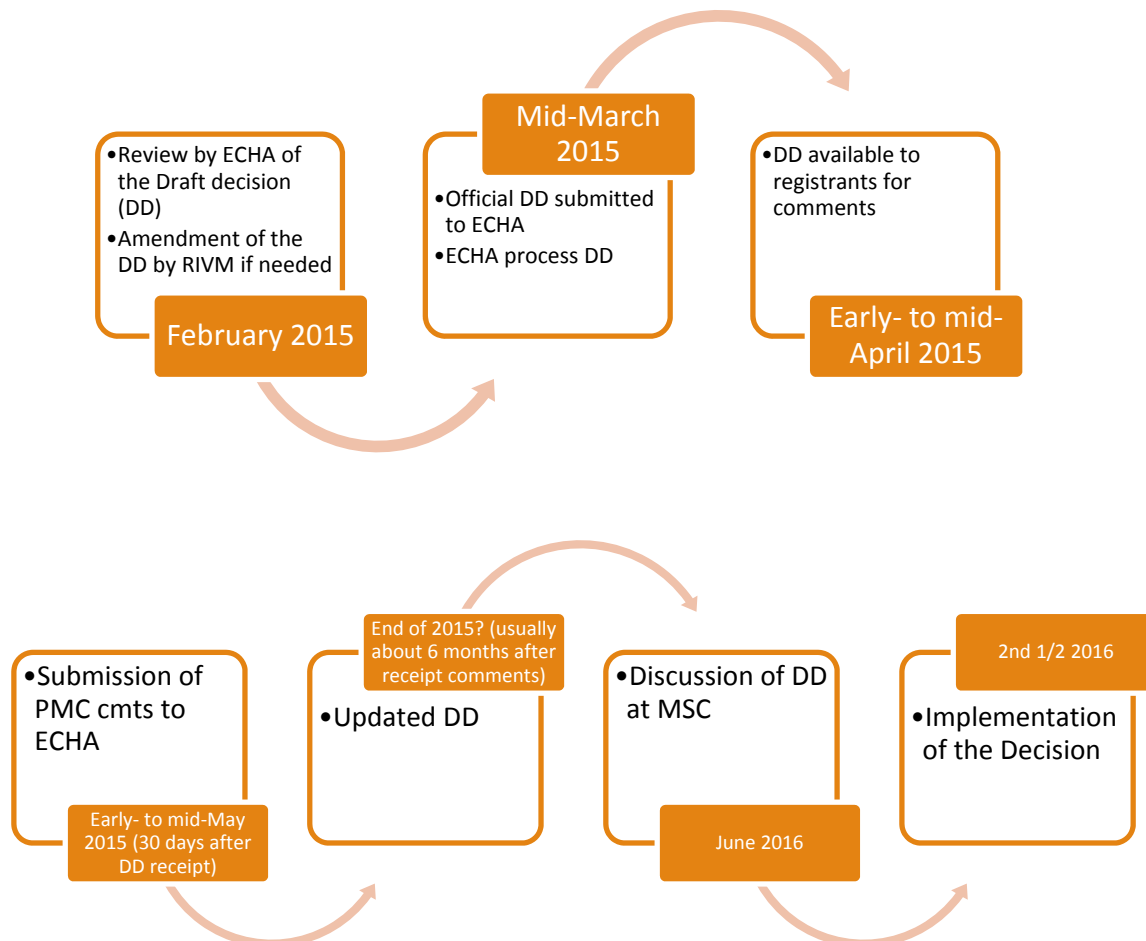
Agenda item 6.a – Silver Evaluation

a) Outcome of the conference call RIVM (17 February 2015)

Participants:

- PMC Secretariat (France Capon, Klaus Rothenbacher, Katrien Arijs)
- Lead Registrant, Aurubis (Daniela Cholakova)
- RIVM (Theo Traas, Eric Bleeker, Maarten Nederveen)

RIVM introduced the conference call explaining the current status and the timeline of the Evaluation process:





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To ensure that the industry is able to comment during the very short consultation period (30 days in April-May 2015), RIVM presented during the conference call the main outline of the DD which reflects the concerns already raised in May 2014:

- Wide dispersive use in Environment: need to have more clarity on the uses (including end uses) and the environmental exposure to nano silver.
- The use of the Ag ion as a worst case for the environmental Risk Assessment: additional (fate) testing will be required to demonstrate that the ion is more toxic than the particles in the environment compartment (aquatic and soil).
- Characterisation of the nanoform registered: each company (not only the LR!) will be invited to provide additional phys-chem data (PSD, surface areas...) to ensure a proper characterisation of the substances as placed on the market.

Overall, **no changes in the position of the NL which remains consistent with previous discussions and need for clarifications.**

b) Next steps

The most important step for PMC will be the consultation period on the DD which will be organized in April-May 2015. In preparation of the consultation:

- By March 2015: PMC will review the previous exchanges with RIVM to prepare the comments to the DD on the ion theory and potential additional related testing requirements
- April 2015: comments drafting (with the support of WCA)
- April 2015: based on the DD and agreed comments, development of an advocacy strategy with MSCAs.
- May 2015: submission of comments to ECHA
- 2nd ½ 2015: start implementation of the decision which is not challenged (e.g.: additional data gathering on uses and characterisation work at company level)
- 2016: finalisation of the Decision and participation to the MSC hearing (June 2016)
- 2016 and beyond: implementation of the final decision