

Ag Project - Dossier Update for Evaluation
 PMC Internal 'To Do List'; version 19 July 2013 (living document)

Final draft for discussion/approval at 4 September 2013 Ag WG meeting

Aim: For PMC Secretariat, Ag WG, and Mgmt Cttee to use as a basis to track progress at every conference call and meeting of the Ag WG as from September 2013

- Following meeting dates will be used to discuss and finalise the various tasks under each milestone
- Agendas will be populated as we get closer to the meeting's date
- All background documents should be circulated to Ag WG one week before the meeting, and ideally a week before that to PMC Secretariat for preliminary review
- Agenda items related to the Evaluation preparation will be separated from those inherent to the maintenance of the Ag project dossiers

Table 1. Meetings of the Ag WG to discuss and agree on Ag Dossier update content before submission in Dec 2013

Meeting	Agenda items	Deliverables to circulated to Ag WG	Deliverables in slides for presentation at mtg
4 September 10:30 - 16:00 Brussels Metals Conference Centre	<ul style="list-style-type: none"> ○ Progress of on-going studies and data-access initiatives ○ Status of key deliverables (DNEL report, PNEC report, ES, CSR, etc.) and next steps ○ Status of and comments on IUCLID 5 file ○ Identification of likely future research needs ○ Preparation of meeting with RIVM on 20 Sep: agenda, key messages, PMC representation, and documents ○ Response to public consultation relative to REACH annexes and nanomaterials ○ ? 	On 28 Aug: COMPLETE	
23 October 10:30 - 16:00 Brussels Metals Conference Centre	<ul style="list-style-type: none"> ○ Progress of on-going studies and data-access initiatives ○ Status of generation/collection of identification and characterisation information from individual registrants ○ Review of draft deliverables (DNEL report, PNEC report, ES, CSR, etc.) and next steps ○ Detailed review of IUCLID 5 file from A to Z, including in particular of sections 1.2, 2 and 3.5 ○ Confirm future research needs for presentation to Mgmt Cttee + circulation to Assembly ○ ? 	On 16 Oct:	
3 December 10:30 - 16:00	<ul style="list-style-type: none"> ○ Approval of final deliverables (DNEL report, PNEC report, ES, CSR, etc.) and finalisation of dossier update 	On 26 Nov:	

Brussels Metals Conference Centre NOTE: The meeting room does not allow conference call participation	<ul style="list-style-type: none">○ Approval of final IUCLID 5 file and dossier update submission steps (Ag and Ag compounds)○ Confirm key messages from Ag WG + future research needs for presentation to Assembly on 4 Dec○ ?		
---	---	--	--

DRAFT

Table 2. Plan to prepare and follow-up preparation for the Substance Evaluation of the Silver Dossier prepared by the Netherlands.
 Colour-code used means: **PMC Secretariat work**, **EBRC work**, **WCA work**, **Post-Evaluation work**
 Letters in first column mean: D for Done and Dd for Delayed

MILESTONE/STEP	WHO?	WHEN?
1. Publication of relevant CoRAP list, ECHA's compliance checks, and other policy-actions	ECHA	20 March 2013
D Monitor publication of draft and final CoRAP lists and associated justification documents	PMC Secretariat	Done since Mar 2013
Monitor outcome of ECHA's compliance check of Ag Dossier (possibly targeting substance identification) and integrate recommendations in update preparation	All	Oct-Nov 2013
Clarify CoRAP list which will confirm timing for Ag's Substance Evaluation (is the March 2013 version definitive or should we wait for the draft Feb 2014 one to be sure our Evaluation will start in Feb 2014?)	PMC Secretariat	Unlikely to change
Share experience with other sectors undergoing Substance Evaluation, such as SAS, TiO ₂ , etc.	PMC Secretariat	On-going
React to request from COM on experience using the latest recommended definition of nanomaterial	All	By 15 Jul 2013 (official deadline)
Provide data on identification and characterisation of nanomaterials to COM (so they can consider during possible review of definition of nanomaterial)	All	By mid-Sep 2013
Respond to public consultation relative to REACH annexes and nanomaterials (after discussion at 4 Sep 2013 meeting and 'alignment' with Eurométaux)	All	By 13 Sep 2013 (official deadline)
2. Establish early (informal) contact with NL	PMC Secretariat	ASAP/On-going
D Identify industry expert participating in RIVM technical discussions (e.g. WK-INS) and arrange exchange with him to understand NL's position and concerns	PMC Secretariat	Done, Wim van Tilborg, call on 23 Apr 2013
D Establish (informal) contact with NL upon release of early CoRAP list versions	PMC Secretariat	Done since Mar 2013
D Follow-up on informal contact with NL via known contacts (reminders) and Eurométaux' network	Eurométaux	Done informally
3. Arrange exchange/meeting with NL and respond to NL's questions	NL	By Feb 2014
D Organise preparatory meeting with PMC representatives in order to review the Agenda, agree on key messages, and identify relevant documents for circulation	PMC Secretariat	4 Sep 2013 9:00-10:30
D Identify possible Agenda items to be proposed to The NL, such as: <ul style="list-style-type: none"> • Timeline, logistics, communication, and roles and responsibilities in preparing for and during Substance Evaluation (RIVM) • Organisation of RIVM services re REACH, Water, OECD activities, and identification of potential bridges across services (RIVM) • Clarification on the grounds for concern on Ag (RIVM) • Ag Dossier update under preparation and Ag research work in progress (PMC) • Interest in joint contribution to OECD CoCam programme after Substance Evaluation? (PMC) 	Ag WG	18 Jul 2013 conference call
Agree on documents to be shared with NL in advance of Substance Evaluation, for example: <ul style="list-style-type: none"> • Pros and cons of 1 versus 2 dossiers • Other? 	Ag WG	4 Sep 2013

MILESTONE/STEP	WHO?	WHEN?
Meet with NL	PMC Secretariat, EBRC, WCA, LR, EM representative(tbd)	Bilthoven (Utrecht), 20 Sep 2013
Prepare letter to thank NL for meeting and respond in writing to questions raised during the meeting	PMC Secretariat	End Sep 2013
Follow-up with regular update e-mails to RIVM?	PMC Secretariat	After key meetings + dossier update submission
Update Ag WG on outcome of meeting with RIVM	PMC Secretariat	23 Oct 2013 Ag WG mtg
4. Substance identification, characterisation, and classification	Ag registrants	By Oct 2013
Identify PMC recommended characterisation techniques based on available guidance, literature, and expertise and circulate to registrants for data generation	PMC	Latest version dated 10 Jul 2013
Generate identification and characterisation data for inclusion in individual registration dossiers and provision to PMC secretariat	Registrants	By early Oct 2013
Monitor REACH-IT mailbox for ECHA communications on targeted compliance checks re substance identification and inform PMC Secretariat on any relevant communication	Registrants	On-going
Report on typical impure/size profiles for all Ag substances to PMC Secretariat to update sections 1.2 and 2 of IUCLID 5 files	Registrants	By early Oct 2013
Compile and aggregate identification, characterisation, and classification data in joint dossier	EBRC	Oct 2013
5. Human health	EBRC	On-going/By Jan 2014 at latest
Perform updated literature search to identify new references to be considered in the Dossier	EBRC	Summer 2013
Obtain data/right to refer or use dataset or publication from NTP	EBRC	On-going, last reminder sent on 7 Jun 2013, continue reminding until 15 Sep 2013
D Provide list of relevant HH endpoints in dataset from RAS Materials/OECD WPNM	EBRC	Done on 11 Jul 2013
D Issue recommendations on additional data needs for discussion by Ag WG at 4 Sep 2013 meeting: <ul style="list-style-type: none"> • Dustiness • Exposure monitoring 	EBRC	26 Aug 2013
Assess ES strategy document from EBRC and respond to mini-survey	Ag WG	26 Aug 2013
Coordinate additional data generation/collection for inclusion in IUCLID 5 /CSR / ES	EBRC	Sep-Oct 2013
Identify new uses and coordinate preparation of ES	EBRC + PMC Secretariat	Sep-Oct 2013
Review DNELs on the basis of new data available and prepare updated DNEL report	EBRC	Oct 2013
Follow-up Eurométaux project on standard phrases for ES of inorganic substances, as part of the review	EBRC	23 Sep 2013 EM ES mtg

MILESTONE/STEP	WHO?	WHEN?
of Chesar (due in ~ 1 year), or as a separate <i>ad hoc</i> project		
Update/prepare HH ES for occupational exposure	EBRC	Oct 2013
Update/prepare HH ES for consumer exposure	EBRC	Oct 2013
Explicitly address cleaning, maintenance, and removal of residuals in all ES	EBRC	Oct 2013
Follow-up Eurométaux activities relative to drafting of standard phrases for ES applicable to inorganics	EBRC	?
Review completion of new section IUCLID 3.5	EBRC + Ag WG	Oct 2013
Consider whether to complete IUCLID 5 section 3.7	EBRC	Oct 2013
Justify and document read-across as per ECHA guidance for each/all endpoints (table matrix) with WCA	EBRC	Oct 2013
Decide whether to use Chesar to generate CSR	Ag WG	Sep 2013
Inform PMC Secretariat every time significant changes have been made to the online Ag Dossiers	EBRC	On-going
Update (Oct) and finalise (Nov) Section 3.5, Phys-Chem and HH sections of IUCLID 5 of Ag metal	EBRC	Nov 2013
Update (Oct) and finalise CSR of Ag metal, including occupational, ENV (from WCA) and Waste ES (from ARCHE)	EBRC	Nov 2013
Update (Oct) and finalise (Nov) Section 3.5, Phys-Chem and HH sections of IUCLID 5 of Ag compounds	EBRC	Jan 2014
Update and finalise CSR and ES of Ag compounds, including occupational, ENV (from WCA) and Waste ES (from ARCHE)	EBRC	Jan 2014
Identify potential future data needs ADD	EBRC	Jan 2014
6. Environment	WCA	On-going/By Jan 2014 at latest
Perform updated literature search to identify new references to be considered in the Dossier	WCA	Summer 2013
Participate in SETAC and other events where nanomaterials and nanoAg is discussed	WCA + PMC Secretariat	When relevant
D Perform <i>ad hoc</i> review focussing on work (co-)published, or supported by NL experts (e.g. RIVM) on Ag to understand NL's position and concerns	WCA	Done by 11 Apr 2013
Obtain data/right to refer or use dataset from NanoFate project: ADD LIST	PMC Secretariat	Summer 2013
Provide list of relevant ENV endpoints in dataset from RAS Materials/OECD WPNM	PMC Secretariat	W/c 22 Jul 2013
Obtain data/right to refer or use nanoAg dataset from CSIRO	PMC Secretariat	Summer 2013
Coordinate Testing Proposal re soil toxicity discussions and testing programme at CSIRO	WCA	Final report due in Nov 2013
Issue recommendations on additional data needs: <ul style="list-style-type: none"> ASRIT/OECD 209 Oyster test 	WCA	Spring 2013
Draft discussion document suggesting outline of testing protocol for 'repeat' oyster test including and discuss with Ag WG	WCA	Aug 2013
Prepare marine SSD proposal including all costs and discuss with Ag WG	WCA	Aug 2013

MILESTONE/STEP	WHO?	WHEN?
Obtain green light from Mgmt Cttee on marine SSD work	PMC Secretariat	Sep 2013
Coordinate additional data generation, finalise studies, and collect resulting dataset for including in IUCLID 5 / CSR / ES	WCA	Summer 2013
Generate marine SSD	WCA	Q1 2014
Generate soil SSD	WCA	Oct 2013
Review PNECs on the basis of new data available/SSD work and prepare updated PNEC report	WCA	Oct 2013
Update/prepare ENV ES (e.g. to cover nanoAg, and using new spERCs, new PNECs, etc.)	WCA	Summer 2013
Circulate Waste ES for review by Ag WG and approval at 4 Sep 2013 Ag WG meeting	PMC Secretariat	28 Aug 2013
Justify and document read-across as per ECHA guidance for each/all endpoints (table matrix) with EBRC	WCA	Oct 2013
Inform PMC Secretariat every time significant changes have been made to the online Ag Dossiers	WCA	On-going
Update (Oct) and finalise (Nov) ENV sections of IUCLID 5 Ag metal	WCA	Nov 2013
Update (Oct) and finalise (Nov) ENV sections of IUCLID 5 Ag compounds	WCA	Jan 2014
Identify future data needs including: <ul style="list-style-type: none"> • Aquatic toxicity acute: Bio-availability correction, BLM, etc.? • Soil toxicity: AgS research with CSIRO, etc. 	WCA	Jan 2014
7. Perform Dossier QA, review, and complete + submit updated Dossiers	PMC Secretariat, Ag WG, Nano TF, and consultants	On-going/By Jan 2014 at latest
Coordinate external data requests with: <ul style="list-style-type: none"> • CSIRO • NanoFate • NTP • RAS Materials 	PMC Secretariat	By Oct 2013
Illustrate production processes of massive, powder and nanoAg for reference in CSR and IUCLID 5 file	PMC Secretariat + Ag WG	Sep 2013
Review and keep up to date PMC Registration Guidance documents	PMC Secretariat	On-going
Add dossier scope in one or more of the following ways: <ul style="list-style-type: none"> • The CSR: top of the document, between front page and part A • The UCLID 5 file: by adding a section under “Type of Substance” in section 1.1 Identification • The dossier header in step 7 of dossier creation: in free text box “Dossier submission remark”, under Dossier name given by user 	EBRC	Oct 2013
Pre-complete sections 1, 2, and 3, and in particular information summarising scope of dossier across registrants: min/max size range, purities, types of morphologies, and coatings; and resulting classifications for each profile	EBRC	Oct 2013
Finalise nanoAg dataset and check all recommendations from COM, ECHA, NL, UBA, etc. on to the best way to report nanomaterials data have been followed in Ag Dossier	PMC Secretariat	Dec 2013
Make sure all copyrights have been respected/compliance can be demonstrated in Ag Dossier	PMC Secretariat	On-going/Dec 2013

MILESTONE/STEP	WHO?	WHEN?
D Make Ag Dossier available online for final check/comments	PMC Secretariat	Done since 2 May 2013
Regularly review Dossier available online and provide comments to PMC Secretariat	Ag WG	On-going
Devise process to review Ag Dossier by internal and/or external experts	PMC Secretariat	4 Sep 2013
Launch Ag Dossier review	PMC Secretariat	Sep 2013
Collect feed-back on Dossier review, discuss with Ag WG, and agree on resulting actions	PMC Secretariat	3 Dec 2013
Finalise content, pass TCC, and send to Ag Dossier to PMC Secretariat	EBRC	W/c 2 Dec 2013
Circulate final Ag Dossier and related documents for final comment to Ag WG	PMC Secretariat	W/c 2 Dec 2013
Check final version of Ag Dossier and send to LR. If further Dossier update required during Evaluation (not recommended), properly flag relevance of update content in: <ul style="list-style-type: none"> • ‘Dossier submission remark’ field in Dossier creation wizard, and • ‘Remarks’ field under ‘Type of Submission’, and • the ‘Other’ justification from the pick-list in the ‘Justification’ field under ‘Type of Submission’ by stating: <i>“relevant for on-going Substance Evaluation”</i> 	PMC Secretariat	W/c 9 Dec 2013
Complete file, pass TCC, generate Ag Dossier, pass TCC, submit to ECHA, and inform PMC	Aurubis	W/c 16 Dec 2013
Make sure all copyrights have been respected/compliance can be demonstrated in Ag Dossier	PMC Secretariat	On-going/Jan 2014
D Make Ag compounds Dossiers available online for final check/comments	PMC Secretariat	Done since 2 May 2013
Finalise content, pass TCC, and send to Ag compounds Dossiers to PMC Secretariat	EBRC	Jan 2014
Check final version of Ag compounds Dossiers and send to LR. If further Dossier update required during Evaluation (not recommended), properly flag relevance of update content in: <ul style="list-style-type: none"> • ‘Dossier submission remark’ field in Dossier creation wizard, and • ‘Remarks’ field under ‘Type of Submission’, and • the ‘Other’ justification from the pick-list in the ‘Justification’ field under ‘Type of Submission’ by stating: <i>“relevant for on-going Substance Evaluation”</i> 	PMC Secretariat	Jan 2014
Complete file, pass TCC, generate Ag compounds Dossiers, pass TCC, submit to ECHA, and inform PMC	Lead Registrants	Jan 2014
8. Other tasks	PMC	On-going
Produce shorter versions of ES for all Ag substances	EBRC & WCA	Oct 2013
Agree on languages in which short ES should be translated and launch translation	Ag WG	Nov 2013
9. Communicate with (potential) registrants/SIEF and public in general	PMC	On-going
Regularly update PMC, (potential) registrants/SIEF, and EM on on-going Evaluation process	PMC Secretariat	At every meeting + bi-monthly e-mails
Keep Silver Institute and any other relevant partner in PlatforM apprised of progress and key outcomes/results of Evaluation process	PMC Secretariat	PlatforM meeting on 28 Sep 2013 + e-mails to Silver Institute
OPTIONAL: Prepare external communication document on behalf of Ag industry (as PMC, and/or with	Ag WG	Jan 2014?

	MILESTONE/STEP	WHO?	WHEN?
	other associations) once dossier update is submitted and send to PMC Members, Wim de Coen, ChemWatch, etc.?		
10.	Consider Draft Decision from NL and prepare response/additional research	PMC	12 mo from start of Evaluation (Q4 2014/Q1 2015)
	<p>Upon receipt of DD and Evaluation Report in IUCLID 5 format by all registrants (~ 4 weeks after it is sent to ECHA) evaluate content and prepare constructive and diplomatic response containing a.o. (and as applicable):</p> <ul style="list-style-type: none"> • Wish to participate as case-owner in discussion on DD at relevant MSC meeting (depending on content of DD, i.e. if proposals for amendments on DD are made) via EM representation only or via EM + PMC representation (no confidentiality concerns since representatives of all registrants with duly signed Confidentiality Agreements in place) • Relevance of the requested study • Selection of test article and possible read-across justification • Who will perform requested studies • Clarify that existing cost- and data-sharing rules are already in place in dedicated Consortium and Letter of Access Agreements, or foreseen to be adapted to remain fair, transparent and non-discriminatory (e.g. nanoAg specific study) • Indication of likely timing of next dossier update (within deadline provided by ECHA, or later if nature of requested study requires more time due to sample availability, laboratory availability, duration of the test, etc.) 		30 days upon release of DD + 30 days upon release of amendments to DD
	Upon receipt of proposed amendments evaluate content and prepare constructive and diplomatic response as per above content		30 days upon release of proposed amendments (but max 15 days after referral)
	Participate in MSC meeting if amendments to DD are proposed by ECHA and/or other MSCA, and PMC invited by ECHA		
	Monitor content of final decision		60 days after referral of proposed amendments
11.	Update Dossier with requested information	PMC	As agreed with NL & ECHA
	Agree on testing scope, protocol, sample, and timing, request samples, and launch study		
	Assess study results and explore update needs (IUCLID 5, CSR, read-across justification paper, etc.)		
	Liaise with other Ag experts (e.g. Silver Institute), EM and NL on study results as relevant		
	Update Dossier as relevant		

MILESTONE/STEP		WHO?	WHEN?
12.	Consider NL's opinion on information provided in response to final decision	PMC	12 mo of info being submitted (2016?)
	Follow-up on NL's recommendations for: <ul style="list-style-type: none"> No further action (if no concerns left), or Further regulatory risk management related action (if concerns left) such as: one registration per form, voluntary action by registrants, other legislations, Authorisation, Restriction, harmonised C&L, OEL setting, etc. 		
13.	Consider joint submission of Ag dataset to OECD	PMC	ASAP after Substance Evaluation
	Invite RIVM to consider possibility of jointly submitting Ag dataset to OECD	PMC	20 Sep 2013 mtg
	Follow-up developments around CoCam programme (may change as from 2015) and adjust strategy as relevant	PMC	On-going
	Prepare/agree on dataset to be submitted to OECD programme	PMC + NL?	2015?