DRAFT DISCUSSION PAPER, dated 25 July 2012

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Table 1. Content of the Dossiers when registering nanoAg under the existing Ag Dossier or in a separate Registration Dossier under REACH

	One Dossier: Silver > 1000 t/a	**Two separate Dossiers: Bulk silver > 1000 t/a Nanosilver 1-10 t/a**
Scope	One unique Registration Dossier addressing all forms of Ag manufactured and/or imported in the EU.	One Registration Dossier for < 100 nm Ag and one for > 100 nm Ag.
Information requirements	Information requirements would be fulfilled for the highest tonnage band (> 1000 t/a, i.e. Annexes VII-X) and the most relevant form, following a worst case/conservative approach. Where one or the other form exposes particular properties which should be addressed separately rather than as part of this worst case approach, a separate endpoint summary would be created in IUCLID 5 for that specific endpoint/property.	Each Dossier would have its respective information requirements triggered by the tonnage band, i.e.: Bulk Ag, > 1000 t/a → Annex VII – Annex X NanoAg, 1-10 t/a → Annex VII
CSR	The existing CSR could be updated to reflect nanoAg or if relevant, a separate CSR could be prepared for nanoAg and submitted in the same IUCLID 5 file.	Bulk Ag → CSR NanoAg → No CSR

Table 2. Pros, cons, and non-assignable aspects of registering nanoAg under the existing Ag Dossier or in a separate Registration Dossier under REACH (Arguments which seem particularly relevant to the credibility and resources of the EPMF/PMC secretariat have been highlighted in yellow)

	One Dossier: Silver > 1000 t/a	**Two separate Dossiers: Bulk silver > 1000 t/a Nanosilver 1-10 t/a**
1. Identifiers	One CAS and EC number (Business As Usual)	Would trigger generation of new EC number for nanoAg and probably require requesting a new CAS number too, which is administratively very burdensome and long (EPMF/PMC resources are already scarce). EPMF would face strong opposition and be involved in very difficult discussions with several precious metal associations and/or their Members (e.g. CEFIC, Eurométaux, IPMI, Silver Institute, SUA, NIA) thereby seriously weakening EPMF's credibility and reputation. It may cause disruption/confusion/unfairness on the Ag market (different reference numbers used in SDS, transport documentation, etc.) worldwide as one unique EC and CAS number has been used for Ag and nanoAg so far. NanoAg manufacturers and importers (mainly outside the EU) may wish to retain the original CAS number for nanoAg claiming that it is Ag manufacturers and importers who claim to have a substance which is different than nanoAg.
2. Registration fees to ECHA	One Registration fee per legal entity manufacturing any form of silver (massive, bulk powder, fine powder, ultrafine powder, nanopowder, or other forms of nanosilver, etc.)	Two Registration fees for legal entities manufacturing both forms
3. Consistency	Massive Ag and Ag powder are already addressed in the same Dossier even if Ag powder has different properties than massive Ag.	Could question whether massive Ag and Ag powder should not have been registered separately too.
4. Coherence / Scientific ground	In any case, information on Ag or nanoAg indirectly affects/benefits the other form. For example, information on nanoAg has already been used in the existing Ag Dossier, thereby reducing costs and resources. Ag and nanoAg are manufactured via similar processes, which are tailored to deliver specific sizes and which can be completed by adding coatings or preparing suspensions for fine powders. They hence result from a common manufacturing process.	Could mean the nanoAg data could no longer be used and actual testing is required on Ag to fill in a data gap which was initially filled with nanoAg information, leading to an increase of costs and necessary resources (e.g. for test planning, monitoring, etc.). Since they result from a common manufacturing process, for the purpose of REACH, notwithstanding the other parameters which need to be considered, they would be registered separately although they are deemed to be the same substance.
5. Burden on LR	One Lead Registrant, who would be responsible to address Dossier updates (with the support of PMC secretariat) for all forms of Ag (administrative burden caused by e.g. nanoAg discussions would fall on (currently) non-nanoAg manufacturer/importer LR). PMC Secretariat would support the Lead Registrant to minimise the burden. A change in LR could be envisaged after the Evaluation phase if this issue was deemed problematic for the current LR. Although known to be feasible, the exact procedure for LR change unknown at this stage.	Two Lead Registrants, each one would be responsible to address Dossier updates (with the support of PMC secretariat) for the relevant form.

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6. OSOR principle	Since Ag and nanoAg are chemically speaking the same substance (i.e. Ag ion), resulting from a common manufacturing process, and have always had the same EC and CAS number, this approach follows the OSOR principle (One Substance, One Registration) laid down in the REACH regulation. It furthermore is in line with the views and position of other industry associations in the EU and abroad (e.g. US). The EC inventory (and as well the CAS inventory) include examples of substances with the same chemical composition (which may have different structures and/or properties which could justify separate registrations) but different EC and CAS numbers, e.g.: (1) diamond, graphite and carbon; (2) various forms of charcoal and carbon black; (3) rutile (TiO_2) and anatase (TiO_2); (4) various forms of silicon dioxide (such as cristobalite, silica vitreous, trimite and quartz); (5) stereo-isomers.	Examples in EC inventory indicate same EC and CAS numbers do not justify sameness/OSOR principle. May be regarded as a deviation from the OSOR principle and set a precedent for/complicate advocacy towards other regulatory frameworks in the EU and abroad (preparing two separate Dossiers implies recognition of Ag and nanoAg being two different substances (based on e.g.: their difference in properties, if any) NGOs could see this as an admission that nanoAg is different and therefore more hazardous, accelerating political pressure to increase the regulatory threshold. EPMF would (again) face strong opposition and be involved in very difficult discussions with several precious metal associations and/or their Members (e.g. CEFIC, Eurométaux, IPMI, Silver Institute, SUA, NIA) thereby sinking EPMF's credibility and reputation.
7. ECHA Guidance and expectations	ECHA expects the nanoform of a substance to be addressed in the Dossier of the bulk form… (http://echa.europa.eu/documents/10162/13632/registration_en.pdf, page 26, last §: "*When the registrant manufactures or imports the substance in the nanoform as well as in the bulk form, the registration dossier should include the information of the substance in both the bulk form and the nanoform*"). In several communications to registrants, ECHA has furthermore stated that: • Article 36(1) of the REACH Regulation requires any registrant to assemble and provide all the information on all size grades it manufactures, imports or places on the market, regardless of the aggregation / agglomeration state of the substance. • This general duty of care requires the determination of the hazardous properties and the subsequent risk characterisation in order to establish the necessary risk management measures irrespective of the physical form of the substance concerned. • The fact that there is still some degree of scientific uncertainty as to the existence or extent of the risks of nano forms of substance does not, by itself, discharge registrants from characterising nano forms in order to carry out their duties under the REACH regulation.	Could be regarded as a deviation from ECHA's guidance and would need to be thoroughly justified, i.e.: - Non-sameness justifications based on intrinsic characteristics of the substances - Registrants providing all available information not running away from higher information requirements linked to a registration in a lower tonnage band
8. Evaluation preparation	Assuming a correct and complete dataset can be included in the Ag Dossier before Feb/Mar 2013, it would (at least partially) satisfy the expectations of NL in the preparation of the Substance Evaluation phase. NL could provide its recommendations as to how to address nanoAg under REACH.	Assuming a correct and complete dataset is compiled before Feb/Mar 2013, it would not be formally part of the dataset available to NL in 2013 to review the information and Evaluate Silver in its several forms but could be provided upon request. This would allow NL to provide its recommendations as to how to address nanoAg under REACH.

	One Dossier: Silver > 1000 t/a	Two separate Dossiers: Bulk silver > 1000 t/a Nanosilver 1-10 t/a
9. Outcome of Evaluation / Precedent-making	Assuming a correct and complete dataset can be included in the Ag Dossier before Feb/Mar 2013, following Evaluation and when all recommendations resulting from the Evaluation of the Ag Dossier have been implemented, the Ag Dossier would be regarded as a closed case and set a precedent for risk assessing nanoAg in the EU. The Ag Dossier would provide the rationale and methodology for performing a risk assessment of nanoAg in the EU and inspire/influence other jurisdictions/initiatives (e.g. OECD). Updates to the Dossier may however still be required if information requirements on the nanoforms under REACH are increased in line with NGOs request.	It could still be subject to Evaluation in due course after submission to ECHA, where the entire science on Ag ion toxicity (assuming at least part of the information would be read-across from the Ag Dossier to the nanoAg Dossier, e.g. for eco-toxicity properties) may be re-questioned by the same or another Rapporteur. It would be influenced iteratively by on-going initiatives in other jurisdictions/initiatives (e.g. OECD) thereby requiring PMC to react/advocate repeatedly in several contexts.
10. Administrative burden	Assuming at least part of the information would be read-across from the Ag Dossier to the nanoAg Dossier, e.g. for eco-toxicity properties, putting all the information in one unique Dossier may be less burdensome than duplicating this information in a separate IUCLID 5 file. Especially where updates are required where only one Dossier would need to be updated and re-submitted to ECHA instead of two. Hence, this would prevent a duplication of costs and resources.	Assuming at least part of the information would be read-across from the Ag Dossier to the nanoAg Dossier, e.g. for eco-toxicity properties, putting the same information in two Dossiers may be more burdensome/seen as a duplication of work (even if part of the IUCLID 5 completion can be done on the basis of pre-completed templates), especially in the situation of updates where the same information may need to be prepared twice and two Dossiers will need to be updated and re-submitted to ECHA. This would hence trigger a duplication of costs and resources.
11. Information requirements	May trigger higher information requirements on nanoAg; PMC would justify why the information included for each REACH endpoints from Annex VII to Annex X (including e.g. testing proposals) was not generated for each form of Ag but only for a representative/reference form of Ag for that specific endpoint. PMC would investigate and document why in certain cases using nanoAg data or a soluble Ag compound data for a given endpoint is scientifically robust, protective and conservative/worst case. PMC would need to demonstrate for each endpoint which form of Ag is the worst case one and why (by generating e.g. surrogate/weight of evidence data such as bio-elution and T/D data for nanoAg which trigger reasonable costs < 100 000 €).	Information requirements for nanoAg limited to those corresponding to the 1-10 t/a tonnage band (i.e. Annex VII). This "pro" may only be limited in time as several stakeholders are requesting the tonnage threshold for nanomaterials to decrease and information requirements to increase. Selection of reference material should also be properly investigated and documented, especially if several forms of nanoAg are included in the same Dossier (e.g. coated versus uncoated).
12. Financials risk	Due to the regulatory interest in nanoAg and uncertainties over its toxicity profile versus bulk forms, PMC might come under pressure to fulfil REACH higher annex testing requirements specifically applied to nanoAg (e.g. chronic inhalation exposure study in rodents, and/or a 2-generation reprotox study). Whether or not the test-waiver arguments currently applied to bulk forms would apply to nanoAg is unknown at this stage. Even if the arguments are adjusted to apply to nanoAg as well, whether authorities will agree with them is unknown. **Best case:** no chronic test is required or chronic data becomes available as part of on-going research programmes (e.g. EPA and OECD WPMNM), no additional cost foreseen **Medium case:** PMC opens scientific debate with relevant authorities in order to further justify validity of the arguments provided and uselessness of chronic testing, which will require time and money **Worst case:** at least one chronic test is required, with a cost of ~1 000 000 €. If this was the case, PMC Agreement foresees sufficient flexibility to adjust the cost-sharing formula and related co-ownership and data access rights as needed	Due to the regulatory interest in nanoAg and uncertainties over its toxicity profile versus bulk forms, PMC might come under pressure to fulfil REACH higher annex testing requirements applied to nanoAg. For example, a chronic inhalation exposure study in rodents, and/or a 2-generation reprotox study. Whether or not the test-waiver arguments currently applied to bulk forms would apply to nanoAg is unknown at this stage. Even if the arguments are adjusted to apply to nanoAg as well, whether authorities will agree to this is unknown. Best case: no chronic test is required or chronic data becomes available as part of on-going research programmes (e.g. EPA and OECD WPMNM), no additional cost foreseen for any Member Worst case: at least one chronic test is required, with a cost of ~1 000 000 €. Only the registrants of nanoAg would be required to support this financial burden.

	One Dossier: Silver > 1000 t/a	Two separate Dossiers: Bulk silver > 1000 t/a Nanosilver 1-10 t/a
13. CSR	If the effect and exposure pattern of both Ag and nanoAg are similar/comparable, existing CSR would require updating and addition of relevant ES for nanoAg. If the effect and exposure pattern of both Ag and nanoAg are different/not comparable, than a separate CSR would need to be generated for nanoAg (and attached in the same IUCLID 5 file).	No CSR would be required (temporarily). It is very likely that a CSR would be required one day under the pressure of certain NGO and MS to requesting the tonnage threshold for nanomaterials to decrease and information requirements to increase. Would this take place, again it would trigger a duplication of costs and resources.
14. NGO & MS perception	May be seen as diluting/hiding the information on nanoAg in a larger Dossier, unless PMC does a thorough assessment of the nanoAg (cf. item 8 above) and reports this clearly for every endpoint in the IUCLID 5 file. May however be preferred by some MS and NGO who would like to see the > 1000 t/a band information requirements applicable to nanoAg.	May be preferred by some MS and NGO as the risk assessment of nanoAg may be more transparent/straightforward to read. It would however not satisfy their demand for information on nanomaterials as the information provided would correspond to the one required for a 1-10 t/a registration and would reinforce their arguments that a separate regime is required for nanomaterials.
15. Cost-sharing under PMC	Cost of generating and including nanoAg content in Ag Dossier (unknown at this stage but likely to be significantly lower than what has been paid for the Ag Dossier so far) would be paid by all PMC Members and LoA purchasers having declared/registered Ag metal and/or nanoAg based on the existing PMC cost-sharing formula. This could be considered to be unfair as two of the biggest registrants of Ag have no interest at all in nanoAg and according to the current cost-sharing formula they would end up paying the biggest share of the cost of the work triggered by the addition of nanoAg to the Dossier. An *ad hoc* deviation to the cost-sharing formula applicable to all PMC Members could be proposed (e.g. equal sharing).	Cost of generating and including nanoAg content in Ag Dossier would be paid by those legal entities having declared/registered nanoAg only.
16. Rights on data	All PMC Members having contributed to the generation and inclusion of the nanoAg content in the Ag Dossier would co-own this information and be authorised to use it for other purposes than REACH. If they would become involved in the manufacture or import of nanoAg, they would already be REACH compliant. If Letters of Access were sold to nanosilver manufacturers/importers registering under REACH, the income would be credited back to all companies have shared the costs involved in the preparation of the Dossier. Since the perception of and attention on nanoAg indirectly affects Ag, there is a benefit in following developments around nanoAg science and regulation even if not manufacturing and/or importing nanoAg.	Only those legal entities having contributed to the generation of the nanoAg Dossier would co-own this information and be authorised to use it for other purposes than REACH, and be credited for the LoA incomes from nanosilver registrants.
17. Competition	Although each registrant is responsible for the proper identification and characterisation of its substances, there is no *ad hoc* need for each registrant to judge which ones of its Ag metal materials are bulk and nanoAg as they would both be addressed by the same Registration Dossier. There would be no issue of ambiguity/subjective decisions by registrants about which Registration to join with which tonnage band as there would be only one Dossier for a total tonnage band.	In the event of two separate Registration Dossiers, each registrant would need to assess each form of Ag it manufactures/imports in order to assign it to the relevant Registration Dossier. This could lead to ambiguity/non-objective decisions by registrants who may be tempted to select the Dossier which is cheaper, poses less challenges, allows continuing Business As Usual with the same CAS and EC number, among others, especially where borderline (e.g. slightly more than 50% of number of particles < 100 nm) cases occur. This would allow more unfair/anti-competitive behaviours.