Preparatory doc. 2: data sharing

1. Cost sharing – remaining issues

1. PMC new membership cost calculation: based on new cost sharing formula or on both formula?

For the LoA, it was decided to use the new cost sharing formula and to apply the total actual costs for the past years and the budget of the ongoing year. For the PMC new membership, we need to define how to proceed and three options have been identified:

- **Option 1: apply the same rules than for the LoA**, which means that the costs to join the PMC or buy an LoA will be similar, the main difference will only remain in the coverage or not of the activities related to Authorization. This will ensure that LoA will not be favored de facto for costs reasons but this will also raise the issue of the reserves. Indeed, applying this system will mean that new PMC members will not have contributed to the reserves of the past years but only to the reserves of the ongoing years. This will also be the case for LoA members and in case of reimbursement or payment holidays, this dimension will have to be taken into account for the allocation of the reserves.
- **Option 2: apply the same rules than to the existing members** (no retroactivity of the cost sharing formula and principles). This will address easily the issue of the reserves but this will hamper the principle agreed in 2015 that joining the consortium should not be more expensive than buying a LoA. On the top, due to the fact that the previous cost sharing formula is not anymore compliant with the new Implementing Act on data sharing, this could be seen as discriminatory by the companies willing to join the consortium.

Based on the above assessment, **the Secretariat recommends to implement option 1**:

- Same rules for PMC new members and LoA buyers
- Ensure that contribution to the reserves is recorded and adequate reimbursement/payment holidays can be attributed to contributors to the reserves.

2. Data provided to non-PMC members

So far, in the LoA agreement, it was not foreseen to provide a copy of the CSR (Chemical Safety Report) to the companies buying a LoA. However, in the communication duties listed under REACH, companies must update their SDS with relevant Exposure Scenarios which are included in the CSR, the Guidance of Safe Use which was provided until now is not sufficient.

Based on the above assessment, **the Secretariat recommends to provide LoA buyers with PDF copy of the CSR to ensure that they have all the information needed to fulfill their requirements under REACH.**

3. LoA per LE or per company?

So far, the LoA have been sold by Legal Entity while the PMC membership is per company. This systems could be acceptable if the cost sharing is done based on the real tonnages but difficult to defend in the case of a tonnage band approach as chosen by the PMC. Moreover, this is also discriminant due to the administrative costs shared by company in the PMC and which would be shared by Legal Entity for non-PMC members. A legal advice on this issue has been requested (see email copied in Annex 1) and the recommendation of K&L Gates is to apply the same system within and outside the PMC.

Based on the above assessment and the legal advice in Annex I, **the Secretariat recommends to sell the LoA to companies listing the Affiliates covered by the LoA in an Annex** (see updated draft LoA agreement – preparatory document 3).

4. LoA sold before changes: retroactive application of new rules or not?

Until now, 33 LoA have been sold (27 for silver and 6 for refinables) to 23 different legal entities. These LoAs have been sold under the previous agreement: different agreement, different principles and different costs sharing formula. Following K&L Gates recommendation (see Annex I), we would need to contact these companies to update the agreement on the fact that the LoA system is now based on company and not anymore on legal entity. Moreover, some of these companies are contacting us back to buy other LoA, and they will realize very quickly that the system has changed. However, asking these companies to amend the existing agreement, will open the question on the retroactive application of the cost sharing formula. At PMC level, it was clearly discussed and agreed that no retroactivity will apply.

Three options:

- **Option1: We stick to the principle of no retroactivity**. It means that what was sold in the past remains how it is and that the new rules are applied only to new LoA and the update of existing LoA. We will have the risk to be faced to data sharing appeal since the system will be seen as discriminatory depending on when LoA's have been bought.
- **Option 2:** We apply the new cost-sharing principle retroactively and propose to the companies who will buy other LoAs to work via credit notes instead of reimbursement. For those who will not buy other LoAs we can wait for 2018-2019 when final costs/revenues of the project will be clearer.
- **Option 3:** We apply the new cost-sharing principle retroactively and contact all the companies proactively.

Based on the above assessment, **the Secretariat recommends option 2**, amending the existing LoA and applying the cost sharing principles retroactively in priority for companies buying other LoA and proactively after 2018-2019 when more clarity on overall costs and revenues will be available. The credit note or invoice will be calculated on the basis of the LoA costs paid minus the updated new LoA costs. An estimation will be provided at the meeting on 14th March.

2. Nanosilver – rationales on the 2016 cost sharing proposal

The Assembly requested the Secretariat to document the rationales on the cost sharing formula for silver in 2016. The following text is proposed for the record:

The Assembly approved in December 2015 the following approach for the sharing of the costs related to nano silver and especially to Evaluation in 2016: payment of the costs related to the Evaluation of nanosilver by all companies of the Ag Sub-Assembly based on a specific cost sharing formula introducing a weighting factor of 5000 for the companies producing nanosilver. This approach is consistent with the spirit of the consortium and the underlying principle of the agreement that cost sharing is based on requirements (e.g.: tonnage, SCC etc.). The factor of 5000 has been selected after the review of the existing weighting factors for tonnage bands (5, 20, 100, 1000) and SCC (1). The proportionality budget versus requirements was assessed. The budget for the overall evaluation is around 5 times higher that the budget for the maintenance of the silver dossier and therefore, it was suggested to multiply the higher weighting factor by 5. This factor has been applied and the results checked by the Assembly and has demonstrated that the approach is fair for nano and non-nano registrants.

This cost sharing formula will apply in 2016 and will be reconsidered in 2017 to check if it is still fair and non-discriminatory for the co-registrants.

Annex I: legal advice LoA per Legal entity

Dear France,

I refer to our discussions regarding the difference of treatment between the Cs Members and the LOA recipients regarding the payment of the administrative fee.

As discussed, under the system currently in place, Cs members pay an administrative fee by company (i.e. a company is only charged for the administrative fees once for itself and its affiliates) while LOA recipients pay by legal entity (i.e. the group parent company and each of its affiliates are obliged to individually pay the fee). Thus, for instance, if a company having 10 affiliates is Cs member, it must only pay once the administrative fee, and if it opts for the acquisition of LOAs, it will have to pay the administrative fee 11 times, each legal entity which forms part of the company's group being obliged to pay it.

We take the view that this system could be deemed as discriminatory for LOA recipients in light of the following rules and principles:

The Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 provides that:

- Costs relating to sharing and jointly submitting information in accordance with Articles 11(1), 19(1), 27(3) and 30(1) of REACH should be determined in a fair, transparent and non-discriminatory manner;
- The costs of sharing data must be justified and adequately distributed between the parties to a data-sharing agreement;
- If the participants to a data-sharing agreement cannot agree to a cost-sharing model, each participant shall pay an equal share of the costs required for their participation.

DCG recommendation entitled "Fair, transparent and non-discriminatory costs sharing in SIEFs" issued by ECHA on 1 October 2014 (note that this DCG recommendation has been superseded by the Commission Implementing Regulation (EU) 2016/9. However, the fairness principles described in this recommendation are likely to remain valid) specifies that:

- Data and their costs need to be shared in a fair manner;
- Assessing fairness of cost sharing should be based on a case by case analysis;
- Cost sharing methodology should always be objectively justifiable;
- Different treatment among SIEF members must be strictly limited to situations that are objectively different;
- In this respect, different prices may be considered in case the scope of granted rights is itself different;
- A price differentiation per tonnage bands and per level of information requirements is mainly applicable to study costs. The way to distribute the "non-study" costs such as administrative expenses, provided these costs are reasonable and not disproportionate, may follow a different approach, e.g. via an equal division between all the co-registrants, regardless of their tonnage band;

- Administrative costs must be reasonable and their basis well recorded and time tracked;
- It must be ensured that cost sharing criteria are carefully explained to SIEF members using coherent and objectively justified methodology that is well documented.

Under the system adopted by the PM Consortium, there is no price differentiation per tonnage band as regards administrative fees. As a result of the difference of treatment between Cs members and the LOA recipients described above, the financial burden of companies opting for the acquisition of LOAs could be much higher and might potentially also be considered as unreasonable and disproportionate in comparison with the administrative fees paid by companies which are Cs members.

Unless this difference of treatment can be objectively and coherently justified (which seems quite unlikely here), this situation could be found as creating a discrimination.

Furthermore, this difference of treatment appears to be in contradiction with ECHA's recommendations above, which insist on the need to provide "equal division between all the co-registrants".

For these reasons, we recommend amending the current system and providing that LOAs are granted per company and no longer per legal entity, in order to align the treatment of LOA recipients and of Cs members.

In case this change would be implemented by the PM Consortium, existing LOA recipients should be requested to sign addendums to their LOA. Further to the signing of these addendums, credit notes should be issued and the concerned LOA recipients should be reimbursed for the overpayments. I understand from our previous discussions that this could be rather easily achieved due to the limited number of existing LOA recipients.

I suggest that we discuss this in further detail at the occasion of our call tomorrow.

Kind regards,

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