Silver Work Group meeting

Draft minutes, Brussels, 2 April 2019 (9:00-12:00 CET)
Chairs: Clémence Siret (SAFT, France) and Rob Garrett (Ames, UK)

1 Welcome and Introduction

1.1 Reminder on Confidentiality and Competition Law

Participants were reminded on their obligation to comply with Confidentiality and Competition Law.

1.2 Tour de table and apologies

The list of participants is available in Annex 1.

1.3 Approval of the agenda

The agenda is available on slide 4 in Annex 2. One addition was made to the agenda after it was circulated: 'LR changes due to Brexit' added under AOB. No remarks / additions; agenda approved.

1.4 Approval of the minutes of the last meeting (10 Oct 2018) and status of action points

No remarks / additions; minutes of the meeting of 10 October were approved. A table with the status of the action points from this meeting is available on slides 6-7 in Annex 2. All action points have appropriately been addressed / are ongoing where possible, or will be discussed in this meeting.

2 WFD prioritisation brief update

Ag has been shortlisted by JRC as candidate priority substance (PS) (STE-score > 1.8) and JRC drafted an EQS dossier for Ag with a freshwater EQS of 10 ng/L versus our REACH PNEC of 40 ng/L. The revision of the PS list has been postponed until after the WFD fitness check / REFIT (i.e. at least until end 2019) and further steps for shortlisted substances as announced in March 2017 by the European Commission (EC) are listed on slide 9 in Annex 2. We currently do not have a clear view on timing from the EC; so far, the REFIT has not progressed as much as expected. Therefore, **we do not expect any actions on the candidate PS before 2020**.

The **confirmation of Ag PNEC/EQS in substance-specific sub-group is currently on hold**:

- There is currently **no lead** of the sub-group. The previous lead was Sweden but since Ann-Sofie Wernersson - who was leading the Ag sub-group discussions for Sweden - left the Swedish Agency for Marine and Water Management end October 2018 and none of her colleagues within the Agency can take over the group's leadership, the EC is looking for a new leader for the Ag sub-group (likely another MS). It was noted that Kemi, who is reviewing the Ag BPR dossiers, is involved in the Ag sub-group discussions but was not leading.
- EPMF contacted **Belgium** (VMM) as possible new lead, but they indicated that they have nor the expertise, nor the time to get involved. Belgium was approached because of the importance of the silver industry in Belgium and because their national EQS is considered reasonable. With regard to other possible MS that could lead, **Germany** is not our favourite option but they are identified for further advocacy actions related to the EQS, as well as **France** and **The Netherlands**. **AP5**
- On 18 October, Sweden sent a **revised Ag EQS dossier** to the Ag sub-group with only 1 week for providing written comments and no time for proper discussion. The revised Ag EQS dossier takes into

account the additional test data generated by EPMF but now disregards other literature data that were previously considered reliable and leads again to a freshwater chronic EQS of 10 ng/L. EPMF has provided comments on this revised dossier, defending again the EQS value of 42 ng/L, and these comments have also been forwarded to the EC, who will send them to the new lead once identified. What will further happen to the Ag EQS dossier is currently still unclear. The only other member of the Ag sub-group that provided comments to the revised Ag EQS dossier was Germany, and they commented that the Sweden proposed EQS is 'plausible'.

The Ag EQS Setting in Sweden is postponed: cf. slide 10 in Annex 2.

The publication on the revised freshwater EQS is ongoing and a platform presentation at the SETAC Annual Meeting in Helsinki (26-30 May) is accepted. The inclusion of the results of the Ag ecotox tests, the updated SSD and updated ERVs in the Ag dossiers is also ongoing. **AP1-3**

Regarding **bioavailability**, an offer by ARCHE for the review of bioavailability effects on chronic Ag toxicity to aquatic organisms is currently under consideration by the EPMF Sec. ARCHE was selected for reasons of continuity (ARCHE has performed the review of the freshwater PNEC and is therefore already familiar with the available literature). The work is already included in the 2019 budget. **AP4**

The **sediment testing** (for derivation of updated $PNEC_{sed}$) has been postponed and budgeted for 2020. **AP7**

3 Second MISA workshop: key conclusions / learnings

Cf. slides 13-15 in Annex 2. Comments/additions:

- Non-MISA participation metals can still **join MISA** (there are some recent newcomers) but the later they join, the more work they have to catch up to the MISA activities and thus fulfil the conditions outlined in the Framework for Cooperation agreement.
- In addition to the 2nd MISA workshop on 7 February, a workshop was held on 8 February on progressing the **Rapid Removal concept for metals classification**. As a result of this workshop, a number of actions were identified (including the development of an extended Transformation / Dissolution protocol) that are currently being followed up by Eurométaux. Given the relevance to Ag classification, EPMF will follow developments and apply the concept to Ag where possible. **AP8**

4 Silver reproductive toxicity

4.1 Recap situation silver reprotox

Cf. Slide 17 in Annex 2. During the CLH process under the BPR, a classification as Repr cat 2 has been agreed for silver zinc zeolite (SZZ) and proposed for some other silver containing active substances (SCAS) and a **classification as reprotox cat 1B has been proposed recently for silver nitrate** (and is expected for elemental Ag). EPMF identified the scientific data gap related to reprotox of Ag already in 2015 by submitting a **testing proposal (TP) for an EOGRTS** with silver acetate (applicable to ionic silver irrespective of the donor silver substance forming this ion). The TP was updated in April 2018 to reflect the most recent scientific data, and in December 2018, the draft decision (DD) on the TP has been sent to the lead registrant. In the DD, the **TP is accepted by ECHA**.

Slide 18 in Annex 2 shows the overlap between the REACH registered Ag substances and the SCAS registered under the BPR by ESTF. This illustrates that regulatory decisions have shared relevance for both sectors. It is recommended to check which forms of elemental Ag are exactly covered under the

BPR / in the elemental Ag CLH proposal (**AP9**). Reference is made to the Cu case, where the BPR only covers the ions generated by the electrodes.

4.2 EOGRTS Testing Proposal: timeline, DD and comments

TP process and timeline is available on slide 19 in Annex 2. The DD was received on 18 December 2018 and comments on the DD were submitted by 8 February 2019 and are now under consideration by ECHA, who may amend the DD accordingly. Afterwards, ECHA will notify the MSCA of the (amended) DD and they will have the chance to submit comments as well. The European Commission has informed us at the meeting of 13 March that the MSCAs have not been notified yet of our DD. Based on the decision-making process, it is anticipated that we will not receive the final decision before June 2019 at the earliest. Our TP could be discussed at the June or October MSC meeting (if the TP is not handled via the written procedure). In any case, **EOGRTS test results would not be available before mid-2021 at the earliest**.

(Post-meeting note: ECHA informed us that the TP is now with the MSCAs - deadline for their comments is 15 April - and that the TP is on the agenda of the June MSC meeting.)

The content of the DD is summarised on slides 20-21 in Annex 2. Regarding our **read-across approach** (read-across from silver acetate (AgAc) to all substances forming ionic silver), ECHA has stated in the DD that it is 'plausible' for the purpose of the TP evaluation but that the eventual validity of the read-across approach will be reassessed once the EOGRTS results are submitted. It is noted that this is in line with DDs received for other substances: ECHA does not make firm conclusions on the read-across approach in the DD / during the TP evaluation. If they state that the approach is 'plausible', this is already a good sign. It is further noted that the EOGRTS in itself will not generate data to support our read-across approach, but together with the EOGRTS results, we can submit other (e.g. toxicokinetic (TK)) data to justify our read-across approach.

Regarding the **dose-level setting** (see also agenda point 4.4), the DD states that the highest dose level shall aim to induce systemic toxicity and dose level selections shall be clearly justified. If there are no relevant data for dose level setting, the results of a dose range finder (DRF) should be reported with the main study.

The DD was discussed at the 19 December Tox Experts meeting and it was decided to only **comment on the time we have for the testing** (extension asked from 24 to 36 months) given the complexity of the study, the need for enabling work and the limited number of labs able to perform the study and their limited availability. Together with our comments, lab statements were submitted justifying the request for additional time. BASF noted that for one of their EOGRTS TPs, the DD mentioned 24 months, they requested additional time and the final decision then mentioned 30 months.

4.3 Enabling study gut microbiome: results

The original aim of the study and the results are summarised on slides 23-29 in Annex 2. Additions / comments:

- While the **biome results** showed some statistically significant effects of AgAc treatment on rats (cf. slide 26 in Annex 2), it is recognised that the observed biome shifts are **not as remarkable as expected based on previous study results** (van den Brule et al. 2016, Williams et al. 2015). There are several possible explanations for this: different mode of administration, different species and / or different silver form (with different TK and different matrix influences). There is also the possibility of a very steep dose-response curve for biome effects. It is noted that the biological relevance of the observed biome changes in the EPMF study still needs to be determined but we need to recognise that the biome results of the study may be of limited use in our defence position around secondary effects.

- Slide 27-28: **ceruloplasmin (Cp) oxidase / Cu levels in serum**:
  - Ceruloplasmin is the major copper-carrying protein in the blood. A clear dose-dependent effect of AgAc treatment on Cp oxidase activities was observed.
  - Serum Cu levels were also depressed in the high-dose groups of both sexes to ± 40-50% of control values (slightly higher depression for males). For comparison: in the high-dose female group (28 mg AgAc/kg bw/d), the serum Cp oxidase activity was depressed to 12% of the control.
  - The inferences of this moderate Cu deficiency regarding reprotox are not clear cut but the link between Cu depletion and reproductive performance is already known. A further complication is that not only Cu levels are affected by AgAc exposure but also Cp and Se (see below) such that potential additive impacts on reproduction become a consideration. From other work, it is known that the structure of Cp can be distorted by Ag so it can no longer transport Cu.
  - The Sprando et al. study did not assess Cu markers, but dev tox was reported at 40 mg AgAc/kg bw/d and the study had a claimed dev tox LOAEL of 4 mg AgAc/kg bw/d.
- Slide 29: **Se levels in serum**:
  - Serum Se levels were depressed in the high-dose groups of both sexes to ± 50-70% of control group means values (slightly higher depression for males).
  - It is known that Se has a major role in healthy reproduction.
  - There is a previous report of Ag treatment effect on Se (Yoshida et al. 1983), that showed a similar Se reduction in plasma (but no reprotox parameters were assessed).
  - As an independent effect, the degree of Se depression in the biome study is probably not sufficient to seriously affect reproductive capacity in males/females (most sensitive parameter of Se in reproduction is the potential for adverse effect on pup growth). However, in the case of Ag we need to be mindful of the **potential for combined effects** factoring in also the Cu/Cp axis (see above).
  - **Se is now confirmed as a parameter in respect of the EOGRTS design** (main study or enabling study).
- A number of investigations and follow-up actions related to the gut biome study are still ongoing: cf. slide 31 in annex 2. So far, it is concluded that **the gut biome study has:**
  - **shown statistically significant AgAc effects on the rat biome although not as remarkable as expected based on previous study results and;**
  - **definitely moved forward our knowledge on AgAc effects on Cp, Cu and Se, and these parameters need to be taken into account for the EOGRTS test design and for further TK work**. There appears to be a **combined effect** on Cu + Cp + Se, and the main question is: at what point does Ag^+ trigger a composite deficiency state which is significant enough to impact on reproduction?

4.4 Science strategy: Ag read-across, TK work, preparation EOGRTS

Ag read-across

Cf. slides 32-34 in Annex 2. Both EPMF and ESTF have performed **bioelution** testing on several Ag compounds in the past but for various reasons, results from these studies are unlikely to predict true bioavailability *in vivo*. Since classification of ionic Ag becomes increasingly likely (at least Repr Cat. 2) and we do not have valid data to support our read-across approach, we need to generate further data ASAP. We need to investigate the **differentiation between elemental Ag and ionic Ag but also**

between elemental bulk Ag (micron plus size) and nanoAg, in order to have evidence-based argumentation against a classification of elemental Ag.

Previously, a tiered strategy was agreed:

- Tier 1: data-mining of existing TK data on reference Ag substances;
- Tier 2: improved *in vitro* (bioelution) studies;
- Tier 3: *in vivo* TK testing.

However, Tier 1 (cf. summaries on slide 34 in Annex 2 and the Ag TK report in Annex 3) showed that, because of the complex interactions of Ag in physiological media, **bioelution test results are not a good predictor of *in vivo* bioavailability for Ag substances** (gross oversimplification of actual *in vivo* situation). Therefore, the Tox Experts agreed at the 19 December meeting that bioelution is not a good basis to justify our read-across and additional ***in vivo* testing will be needed** to shed further light on the potential to differentiate the effects observed with soluble silver compounds from elemental silver. Furthermore, given the CLH proposal for silver nitrate and the expected CLH proposal for elemental silver, we need results soon and we cannot afford to lose time with testing that will probably not yield the necessary results.

This approach was also discussed with ESTF on 19 December (joint Tox Experts meeting EPMF + ESTF) and they agreed that further *in vivo* TK testing is needed and they are interested to participate to the testing with Ag substances relevant to them (some are of shared interest to EPMF and ESTF).

(Post-meeting note: A 'Tox Experts group' folder has been created under the meeting files folder on the EPMF website member area, accessible to all Ag WG members, where all meeting minutes, slides and background documents will be stored.)

TK work

Cf. slide 35 in Annex 2. As stated above, a **comparative *in vivo* TK study** is considered essential to support our read-across approach. Key substances to be included in the TK testing are: AgAc, $AgNO_3$, elemental Ag (≥ micron-sized) and elemental nanoAg (+ possibly AgCl and Ag2O).

For elemental nanoAg, it is suggested to test the smallest form. It will be important to correctly identify the elemental micron-sized Ag to be tested for TK (**AP10**)

Preparation EOGRTS

Dose-level setting: cf. slides 36-38 in Annex 2:

- Taking into account also the recent results from the gut biome study, the Tox Experts discussed at their 15 March meeting the available dose level versus effect information for Ag (see slide 37) and they agreed that **currently available effect data are insufficient for definitive dose setting for the EOGRTS and further DRF work is needed**.
- Given dietary admin for the EOGRTS, enabling DRF work has to be configured accordingly. A disadvantage of dietary admin is that you cannot get the same precision than with gavage so we will need to be careful in selecting a lab.
- In the Williams et al. study (using gavage), 'some toxicity' was observed at 100 mg AgAc/kg bw/d. Whether this is replicated using dietary admin is to be determined but given the expected higher bioavailability of gavage vs dietary admin, we would have to dose higher. The Tox Experts suggested 125 mg AgAc/kg bw/d as high-dose for the DRF. A total of 4 doses was suggested to ensure proper identification NOAEL/LOAEL (125 - 40 - 13 - 4 mg AgAc/kg bw/d). At the WG meeting, it is suggested to **dose higher than 125 mg AgAc/kg bw/d for the DRF to ensure we see effects at the high**

dose (150? 175?). Based on the DRF results, we could then still decide to lower the high dose for the actual EOGRTS. AP11

Proposed study design for further *in vivo* testing (cf. slide 39 in Annex 2):

- **Dietary OECD 422 study with AgAc as DRF**, measuring the usual parameters + Cu, Se, Cp parameters (given biome study has confirmed importance of Ag^+ effect on Cu, Se, Cp) + TK parameters.
- Since dietary administration has some disadvantages for TK testing, **concurrent gavage / i.v. TK studies (~OECD 417) for AgAc, $AgNO_3$, elemental Ag (≥ micro), and elemental nanoAg** are suggested. Repeated dosing is suggested for the TK studies, in order to reach steady-state.

The details of the testing need to be further discussed by the Tox Experts, but **the Ag WG agrees to the general outline of the DRF/TK testing, considers this high priority and recommends to start testing ASAP.** AP11

It is noted that at least 6 months are needed to have results of an OECD 422 study.

It is further noted that we do not need to await the TP final decision before starting the testing: the ECHA guidelines on dossier evaluation mention '*Note that if you wish to perform preliminary studies (e.g. palatability studies, dose range-finding studies), you do not need to wait to receive the adopted decision and can already initiate them*'.

5 CLH proposal silver nitrate

CLH process and timeline is available on slide 41 in Annex 2. Kemi has submitted the CLH proposal for silver nitrate in December 2018 and it is currently still in the accordance check phase. As soon as the dossier is compliant, the public consultation will start and 18 months later the RAC opinion has to be available. This means that the **RAC opinion on the silver nitrate CLH may be available before our EOGRTS test results are available**.

The suggested approach for comments on the silver nitrate CLH is summarised on slides 42-43 in Annex 2. Comments/additions:

- **Skin Corr 1B vs 1A**: It is noted that $AgNO_3$ has its own UN number, so it is expected that a classification change would not have a major impact in the short term. However, over time, the updated classification would need to be implemented. Companies are asked to check the impact of a Skin Corr 1A classification for $AgNO_3$ internally (AP12) so the EPMF Secretariat can decide whether they need to comment on the Skin Corr 1A classification proposal. It is suggested to still raise our arguments during the public consultation if possible but focus on other endpoints in priority.

The Ag WG agrees to the suggested commenting strategy.

6 Advocacy strategy silver reprotox

Cf. slides 46-52 in Annex 2 and documents in the 'Ag CLH proposal advocacy' folder under the meeting files folder on the EPMF website member area:

- A CLH proposal for elemental Ag will be submitted by Kemi somewhere in spring and the EPMF Secretariat is preparing for several actions / communications to DUs.
- Carol Mackie was previously approached for support regarding advocacy but given recent (quick) developments around the CLH proposals and the TP and the importance to members, it was decided to take this back in house and the contract with Carol Mackie was terminated.

- **The EPMF strategy regarding reprotoxicity is to defend our TP and delay the CLH proposals where possible, in order to have a sound science based classification**. For the TP, we cannot contact MSC but there is an opportunity to interact with key MSCAs to secure our TP despite the CLH proposal (there is a risk that some MSCAs think the TP is not needed because of CLH). In our messages, it is suggested to highlight the non-harmonised processes.
- EPMF met with different authorities:
    - Meeting with **ECHA**: EPMF requested to organise a joint meeting with all involved actors Ag REACH / BPR / CLH. ECHA replied that they cannot bring all actors together but they suggested bilateral meetings.
    - Meeting with **European Commission (EC)** (minutes + slides on EPMF website member area): DG SANTE confirmed that Kemi is under time pressure and needs the RAC opinion on the CLH to be able to go to the BPC, and they cannot delay the CLH process. However, EC was understanding of EPMF's concerns and is willing to check the feasibility to ask critical questions to RAC around the data gaps. In order to do this, they need to have a clear view on the reprotox data gaps and how the EOGRTS will address these. Therefore, EPMF prepared a table and sent this to the Commission (cf. summary table included in stakeholders mapping and advocacy tracker on EPMF website member area). France Capon will follow up with ECHA and EC (**AP13**).

  (Post-meeting note: France Capon met with ECHA on 4th April 2019. They recommended to contact the Head of Unit of the Biocides Unit, Klaus Berend to discuss again the different processes and try to find a compromise. However, Klaus Berend replied that the issue was already thoroughly discussed at the 13 March EC meeting and recommended again to raise our arguments during the public consultation to ensure they are considered by RAC in their opinion. DG Grow reacted also on the fact that Kemi acknowledged during the conference call that the dataset was insufficient and requested some clarifications. We are now waiting for the feedback on the summary table on the added value of the EOGRTS.)
    - Call with **Kemi** (minutes + slides on EPMF website member area): EPMF originally requested a meeting with the BPR and CLH people but only the BPR people were on the call. Kemi confirmed that current data is insufficient for classification and Kemi confirmed their strategy to propose Repr 1B to address the issue around the carcinogenicity / mutagenicity data gaps (if RAC agrees on Repr 1B, the substance fulfils exclusion criteria under the BPR and further C/M testing becomes unnecessary).

  (Post-meeting note: Following the approval and sharing of the minutes with EC and ECHA, Kemi requested a clarification to the statement that current data is insufficient, as this statement directly after the EOGRTS discussion could be inferred to mean that Kemi considered the data situation for reproductive toxicity to be inadequate. What Kemi actually meant is that they agreed that gaps exist in the dataset for silver substances (and that therefore all new studies addressing these gaps would be welcome). The minutes were updated accordingly and shared again with EC and ECHA.)
- It was noted that ESTF is not taking a lot of political actions. EPMF decided to meet with the authorities without ESTF for credibility reasons.
- EPMF started a **stakeholders mapping** (cf. stakeholders mapping and advocacy tracker on EPMF website member area):
    - This is a living document to be updated further (as some of the data is from 2018). It lists stakeholders within industry, within Commission / ECHA and key MS.

- **Key MS are considered Belgium, Germany, Italy, Poland and Sweden**. This prioritisation is based on the country's economical interest in Ag, the influence they could have at MSCA level and their available network. The EPMF Secretariat already contacted a series of national organisations (BE, FR, DE, IT, FI) to check which people to contact and KGHM already contacted the Polish authorities (REACH helpdesk). The abovementioned table provided to EC and the slides prepared for the interactions with EC and Kemi are considered a good basis to provide stakeholders with further information.
- It is suggested to also include reprotox experts within MS. Therefore, **the Netherlands** should also be added as key MS in the prioritisation + add Unilever as contact (N. Rajapakse to send contact details – **AP15**). It is noted that Glencore, Aurubis and Johnson Matthey have sites in the Netherlands.
- The UK has not been contacted yet but the plan is to use the cross-sector group on REACH (channel to try to find new contacts).
- For the national federations, it is suggested to include key company contacts under contact details (for Bulgaria, D. Cholakova wishes to be included).
- How and when do we communicate to DUs? The DU communication plan needs to be updated. A statement and Q&A have been already prepared, to be used as soon as the intention of Kemi to classify elemental silver as reprotox cat 1B will be publicly available (on EPMF website member area). The Ag WG would prefer to first inform their customers before EPMF starts DU communication. Therefore, EPMF Secretariat will draft a letter for Ag WG member companies to send to their customers (**AP17**). It is suggested that this letter includes the possibility for companies to get involved in the advocacy process.

(Post-meeting note: Since the CLH proposal has not yet been submitted and the consultation of the MSCAs on EPMF TPs is already ongoing, it is suggested to wait now for the PfAs to better target the MS in preparation of the MSC meeting of June 2019)

- It is noted that the CLH accordance check is mainly on formatting and template, not so much content based. There needs to be sufficient data for classification and this is not the case for Ag. EPMF Secretariat will remind ECHA of this and will also send the minutes of the Kemi call to ECHA as they agreed that current data is insufficient (**AP13**).
- It is suggested to create an Ag advocacy group to be able to react quickly to the latest developments and ensure that the EPMF Secretariat receives the adequate input of the members in a short period of time. The Ag WG agrees but suggests to rename to **Ag advocacy network.**
- **The Ag WG approves the suggested advocacy strategy and the messages to pass (statement and advocacy tracker), and agrees to the EPMF Secretariat continuing to contact the different stakeholders and DUs.**
- Agreed actions by the Ag WG (**AP14-18**):
  - Ag WG member volunteers to confirm their involvement in the Ag advocacy network;
  - Ag WG members to give further input on stakeholders mapping;
  - EPMF Secretariat to continue contacting different stakeholders;
  - EPMF Secretariat to draft letter that companies can use to contact their customers;
  - Start broader communication at DU level 1 month after above letter has been sent.

7 Inclusion of silver acetate (AgAc) in the EPMF portfolio

Cf. slide 54 in Annex 2. There is interest from one Ag WG member and one LoA buyer for registering AgAc in the 1-10 T/A tonnage band. **The Ag WG agrees that AgAc is a critical substance (test substance EOGRTS) and we should try to keep the registration in house.** EPMF already performed a data gap analysis and once the interested companies have confirmed their interest, EPMF will start further testing and dossier preparation.

8 Workplan and budget 2020

Cf. slides 56-57 in Annex 2. The 'dossier maintenance' budget for 2020 includes a literature review, genetox testing preparation (support from prof. Kirkland + possibly development of a TP) and sediment testing (budgeted already in 2018 but not in allocated reserves so will not be invoiced but will be taken from the surplus). We may need to start the genetox testing preparation before 2020 but it is noted that for Ag, we have surplus available so if urgent work is identified that is not already included in the budget, we can use this surplus and budget later (this also applies to DRF/TK testing if the budgeted amount is insufficient).

One of the main tasks foreseen for 2020 is of course the EOGRTS but this was already budgeted previously so is not included in the 2020 budget.

The Ag WG agrees to the proposed 2020 draft budget.

9 AOB, next meetings/calls and closing remarks

9.1 LR changes due to Brexit

Cf. slide 59 in Annex 2. As a result of the Brexit, Johnson Matthey decided to step back from the LR position for silver carbonate and disilver(1+) sulphate. Saxonia and Metalor are proposed as new LRs for these substances respectively. Metalor confirmed their willingness to take over the LR position but Saxonia has not replied yet (but they are the only remaining co-registrant) (**AP**). The WG agrees to the suggested LR changes, which will be sent to the Assembly for approval.

(Post-meeting note: Saxonia accepted the role of LR, Assembly approved.)

Annexes

1. List of participants
2. Slides presented at the meeting
3. Ag TK report 'Assessment of silver toxicokinetic parameters: desktop review and critique of key published data' (M. Raffray, 21 Jan 2019)

Actions

Table 1. Actions agreed at the 2 April 2019 Ag Work Group meeting in Brussels

	What?	Who?	When?
Water Framework Directive (WFD) silver prioritisation			
1.	Publish results additional freshwater ecotox tests and impact on SSD in peer-reviewed scientific journal	EPMF Sec	ASAP
2.	Include results Ag ecotox tests + updated SSD + updated ERVs in Ag dossiers	EPMF Sec	Q2-Q3 2019

3.	Re-check the exposure data / modelling and re-calculate RCRs	EPMF Sec with Ag registrants	Q2-Q3 2019
4.	Literature study on mitigating parameters affecting chronic tox of Ag towards freshwater organisms	EPMF Sec (with ARCHE)	Q2-Q3 2019
5.	Initiate contacts / organise meetings with key MS for advocacy	EPMF Sec (with national industry organisations)	Q3-Q4 2019
6.	Check marine dataset for EQS derivation and suggest additional testing if needed	EPMF Sec	Q2-Q3 2019
7.	Request offers for well-designed sediment tests for derivation $PNEC_{sed}$ (long term, 3 species, natural sediments low in AVS/OC)	EPMF Sec	2020
8.	Follow-up developments at Eurométaux level on Rapid Removal concept for metals classification + apply to Ag	EPMF Sec	As needed
Silver reproductive toxicity – science			
9.	Check which elemental Ag forms are covered exactly under the BPR / in the elemental Ag CLH proposal	EPMF Sec	When elemental Ag CLH proposal is available
10.	Identify elemental micron-sized Ag to be tested for TK based on data currently in Ag dossier + input registrants	EPMF Sec	ASAP
11.	Organise Tox Experts discussion to discuss details of DRF/TK testing (including discussion high dose) and contact testing labs in order to start testing ASAP	EPMF Sec	ASAP
CLH proposal silver nitrate			
12.	Check the impact of a Skin Corr 1A classification for $AgNO_3$ internally	$AgNO_3$ registrants	Apr 2019
Silver reproductive toxicity – advocacy			
13.	Follow-up contacts with ECHA and European Commission; inform them on outcome Kemi call	EPMF Sec	ASAP
14.	Volunteers to confirm involvement in Ag advocacy network	Ag WG members	ASAP
15.	Give further input on stakeholders mapping + N. Rajapakse to send contact details Unilever	Ag WG members	ASAP
16.	Continue contacting different stakeholders	EPMF Sec	ASAP
17.	Draft letter for Ag WG member companies to send to their customers	EPMF Sec	ASAP
18.	Start broader communication at DU level	EPMF Sec	1 month after AP17