



# Ag&Ag cmpds WG/Platforms Call

*Minutes, Call 19 December 2019 (11:30-12:30 CET)*

## **Participants:**

Eliot Deag, Rikki Gordon and Nissanka Rajapakse (JM), Adam Troll (Dupont), Michael Thiel and Olga Lemke (BASF), Michael Huber (C-Hafner), Wasma Al-Husainy (Shell), Herbert Fuchs, Roland Brasch and Arno Buthe (Heraeus), Steven Verberckmoes and Sylvaine Duarri D'Haene (Umicore), Daniela Cholakova and Jorn Muhlenfeld (Aurubis), Rob Garrett (Ames), Clémence Siret (SAFT), Jelle Mertens (EPMF)

Jelle Mertens introduced the topic & discussion (cfr. Slides in Annex 1 of these minutes):

-coverage of the carcinogenicity endpoint in the SCAS (Silver Containing Active Substances) dossiers under the Biocides Directive and in the EU REACH dossiers,

-the intended way-forward of the ESTF regarding coverage of carcinogenicity in the non-zeolite SCAS (i.e. read-across from the existing carcinogenicity study with silver zinc zeolite by generating in vivo toxicokinetic data), and

-the main uncertainties and questions the EPMF secretariat identified with this ESTF approach based on our experience with read-across under REACH.

It is important to note that, if an experimental study for this endpoint with a soluble Ag compound is requested under the Biocides directive, the EPMF needs to get access to this study and include in the Ag&Ag cmpds REACH dossiers. Any potential consequences have to be considered for the classification and labelling of these substances. On slide n° 18, the main (temporary) conclusions and strategic recommendations by the EPMF secretariat are summarised.

During the discussion with the participants:

- It is clarified that the EPMF secretariat has already been in contact with the ESTF regarding this specific topic (and will also in the future be in close contact). We offered the ESTF secretariat our help in drafting input for KEMI to avoid performing the 2-year carcinogenicity study.
- all participants agree that we should –at first- try to avoid the need to perform a carcinogenicity study.

In this respect:

- We need to liaise actively with ESTF to try to convince KEMI & the Biocides WG that a carcinogenicity test is not needed, and that other means like additional TK testing by ESTF, the EPMF ongoing TK testing, the Ag mutagenicity data and the lack of human evidence for a carcinogenic potential of Ag, are sufficient to fill the endpoint
- This input needs to be submitted by ESTF to KEMI by mid January 2020, so quick actions are required.
- we need to contact people of the Biocides WG and/or Biocides Committee (ideally first half Jan 2020) and try to convince them of the above as well (i.e. no need to perform additional carcinogenicity test for Ag substances/SCAS)
- The existing carcinogenicity test with Silver Zinc Zeolite needs to be carefully reviewed to clarify the potential effect of Ag vs secondary effects (Zn? Zeolite?), plus the silver REACH dossiers need



to be checked as well to familiarise with the relevant mammalian tox data (e.g. mutagenicity data referred to in waiving statement).

If the obligation to perform a carcinogenicity study under the Biocides Directive is decided by the Biocides Committee:

- the EPMF experts need to be active as from the first discussions about test design to test report review & finalisation, as the technical expertise at ESTF level is questionable.
- the recommendation to the EPMF board and Assembly in this case is to be actively involved in the study (financial and technical – to be discussed in future meeting)

**The agreed way forward:**

At first, we need to **try to avoid** the request for a carcinogenicity test

- Contact ESTF and review/complement their input to KEMI (<mid Jan 2020)
- Contact Biocides WG experts (if possible) and inform about the EPMF data/approach related to the carcinogenicity endpoint under EU REACH – ECI will be contacted because of their earlier experiences with Biocides dossiers.

If KEMI & the Biocides Working Group & Committee can not be convinced of an alternative way-forward to fill the endpoint than testing, and a **carcinogenicity test is required** under the Biocides Directive, the recommendation of the group to the EPMF Board and Assembly is to get actively involved in the study as from the start.



## Annex I

Slides presented during the call and shared with the participants ahead of the call.



Ag Carcino Heads-up  
Conf Call\_Slides.pdf