

WGMO-2
Final minutes
14.12.2017

Minutes of Ad hoc Working Group Micro-organisms WGMO-2

8 September 2017

Meeting of the Biocidal Products Committee Ad hoc Working Group Micro-organisms

Ad hoc WG Micro-organisms (Ad hoc WG MO)

1. Welcome and apologies

The Chair welcomed all participants to the 2nd Ad hoc WG MO meeting. Eight members participated in the meeting. In addition there were five experts from the eCA present.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes, and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Annex 1.

2. Administrative issues

SECR gave a brief summary on the administrative issues.

3. Agreement of the agenda

3.1 Agreement of the agenda

The Chair introduced the agenda items. Members agreed on the proposed agenda.

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflict of interest to the agenda items. None were declared.

5. Discussion of active substances

5.1 *Willaertia magna* c2c maky (eCA FR)

The Ad hoc WG MO agreed on eight open points. The discussion of the remaining open points will continue according to [active substance process flow 21](#).

6. Guidance development

6.1 Status of guidance development for technical equivalence assessment of microorganisms

The Chair introduced briefly the status of the guidance development for technical equivalence (TE) assessment of microbial active substances. Some open issues related to the guidance were identified in WGMO-1 meeting 28 March 2017, and an e-consultation with eight questions was launched to Ad hoc WG MO members 26 April 2017. Comments were received from CH, NL, DE-BAuA, DE-UBA, SE and Cefic. In summary, the view of the e-consultation was that only TE assessment of identical strains should be included in the guidance, i.e. when there is a change in the manufacturing location or manufacturing process; that all different micro-organisms should be in the scope of the guidance; and that a tiered approach could be used in the assessment. Most opinions were also in favour of applying the Tier I requirements taken from EFSA TE guidance for biopesticides. There were some differences in the views on whether identity of the strain needs to be proven in TE assessment with a change in the manufacturing location or process, and in whether these changes can affect the capacity of toxin production of a specific strain. In general the opinion was, however, that both strain content and toxin content or biopotency (when toxin is the mode of action) should be considered in the assessment. The view was also that impurity metabolites and toxins should be assessed, but only the relevant ones, i.e. the ones assessed in the CAR. FR brought up in the meeting that the scope of the guidance should cover also TE applications from a different source (i.e. a different manufacturer).

Draft guidance is currently being prepared by ECHA, and the comments received from the Ad hoc WG MO are taken into account in drafting. When ready, the draft will be submitted

for commenting to Ad hoc WG MO. After the commenting period there will be a WG discussion.

7. AOB

7.1 Updating IUCLID 6 to better address microbial active substances

The Chair gave a brief update on the discrepancies in IUCLID 6 concerning the BPR information requirements for micro-organisms. The next IUCLID 6 release containing format changes is foreseen for October 2018, and the requirements for the update have to be finalised by April 2018. Ad hoc WG MO will be later consulted on the relevance and nature of changes proposed to IUCLID 6 to better address micro-organisms.

7.2 Other information

The Chair informed about an e-consultation on whether certain nematode species would be regulated by the BPR when used as a biocidal active substance. A summary prepared by DE of the answers received has been uploaded to S-CIRCABC, and the discussion will be continued in the following Ad hoc WG MO meetings. The timing of the next meeting(s) is under discussion and will be set at the earliest possible.

List of Attendees

Ad hoc Working Group Microorganisms

Members	ECHA Staff
BOSMAN-HOEFAKKER Saskia (NL)	PRIHA Outi (Chair)
BOUBAKER Baia (FR)	AIRAKSINEN Antero
STRACZEK Anne (FR)	ESTEVAN-MARTINEZ Carmen
DIETERICH Frank (DE)	GUTIERREZ-ALONSO Simon
KEHRER Anja (DE)	SZYMANKIEWICZ Katarzyna
FONNESBECH VOGEL Birte (DK)	SCHAKIR Yasmin
HENRIKSSON Rebecca (SE)	
NUTI Marco (IT)	Applicants
Rapporteurs / experts	Amoéba
ATTIG Isabelle (FR)	
CHEZEAU Aurélie (FR)	
LEFRANC Agnes (FR)	
MAXIMILIAN Yann (FR)	
ZEROUALA Ahmed-Chaouki (FR)	