WGMO-1
Final minutes
8.5.2017

Minutes of Ad hoc Working Group Microorganisms WGMO-1

28 March 2017

Meeting of the Biocidal Products Committee Ad hoc Working Group Microorganisms

Ad hoc WG Microorganisms (Ad hoc WG MO)

1. Welcome and apologies

The Chair welcomed all participants to the 1st Ad hoc WG MO meeting. Twelve out of the 14 members and one additional expert participated in the meeting.

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. S-CIRCABC Interest Group has been created to share Ad hoc WG MO related documents. The SECR also informed that for possible physical meetings, one member per eCA will be reimbursed for flights and accommodation (not for daily subsistence allowance). WebEx participation to physical meetings will be considered case-by-case.

3. Agreement of the agenda

3.1 Agreement of the agenda

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

3.2 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.

4. Introduction of the members of the Ad hoc WG MO

A tour-de-table was done where each of the participants of the meeting briefly introduced themselves, their background and expertise.

5. Scope and future tasks of the Ad hoc WG MO

The Chair gave an introduction of the scope and tasks of the Ad hoc WG MO. This Ad hoc WG has been established in order to use the specific expertise in discussions on microbial active substances. Fourteen members from eight MSCAs (Denmark, France, Germany, Italy, the Netherlands, UK, Sweden, and Switzerland) have been nominated. The members are nominated until further notice, and without distinction between core members and flexible members. FR enquired whether, due to the wide expertise needed in this Ad hoc WG, the members could be alternating. The Chair clarified that due to the nomination procedure this is not encouraged by ECHA, but reminded that even up to four members from MS can be nominated, and for substance discussions a rapporteur and an additional expert may participate.

The scope of the WG covers matters related to biocides containing microorganisms (microbial active substances). It is foreseen that the scientific peer review of microbial active substances will be done solely in the Ad hoc WG MO, and there will be no discussions in the permanent Biocidal Products Committee (BPC) Working Groups. The Chair mentioned that there are currently five approved microbial active substances, belonging to the bacterial genus *Bacillus* spp. It was noted that also one fungus, *Pythium oligandrum*, has been included in the Union list of approved substances. In addition, a CAR on a protozoa *Willaertia magna* subsp. c2c maky has been submitted to ECHA. The assessment of this dossier was briefly introduced by the eCA under agenda item 7.1.

The Ad hoc WG MO is also expected to identify the needs to develop/revise the existing guidance documents on active microorganisms and contribute to the

development/revision, where appropriate. The current need for guidance development for technical equivalence assessment of microorganisms was introduced under agenda item 6. IT enquired whether there are plans to update the BPR Vol V Guidance on Microorganisms. The Chair explained that as the last revision of the guidance is from August 2016, there are at the moment no plans for a revision.

6. Guidance development

6.1 Development of guidance for technical equivalence assessment of microorganisms

The Chair introduced the status of the current guidance for technical equivalence assessment of biocidal active substances. The guidance dates from 2013, and is in the process of being updated. The current guidance does not cover active substances that are microorganisms, and a separate document for microorganisms technical equivalence assessment is going to be developed. The existing EFSA guidance (Guidance document for the assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates approved under regulation (EC) No 1107/2009) could be considered as a starting point for the corresponding BPR guidance. ECHA is establishing contact with EFSA on this matter.

The Chair identified some foreseen challenges concerning the guidance development:

- How should the strain level approval of active substances be reflected in technical equivalence assessment? The guidance is planned to cover TE applications for a change of manufacturing process or location. Should/can also applications from a different manufacturer (different source) be addressed in the guidance?
- With most authorised bacterial biocides the active substance is not the bacterium itself, but the toxin it produces, so should in TE assessment the identity and content of both the strain and the toxin be considered equally?
- For the identification of strains, should whole genome sequencing be requested, and for metabolites, should presence of the gene and/or its expression be considered?
- Regarding contaminant levels, there is an OECD issue paper on microbial contaminant limits for microbial pest control products (Series on Pesticides No. 65), which some of the applicants refer to. Nevertheless, the BPR Microorganisms guidance states that this issue paper is not an actual guidance document, and that it cannot be directly applied to biocides because it is intended for plant protection products.
- To which extent should/can other organisms besides bacteria be addressed in the guidance?

The members shared some views of these issues and on the guidance development. FR brought up that the most critical issue is the strain identification, since TE applications coming from a different manufacturer may involve a strain with a different culture collection number. DE noted that for content, cfu:s (colony forming units) should be determined, but for efficacy ITUs (International Toxic Units) are necessary. It was agreed that ECHA will draft a list of items to be specifically covered by the guidance, and will send it for comments for the Ad hoc WG MO members by a written procedure. The members will be invited to comment the issues and to offer to participate in the guidance drafting process.

7. AOB

7.1 Introduction to the assessment of *Willaertia* subsp. *magna* c2c maky dossier (FR)

FR gave a brief introduction on the assessment of the dossier. Due to the specific nature of the microorganism in question, the MSCAs are particularly encouraged to involve all relevant experts in the commenting phase. The discussion will follow the timelines for the peer review of active substance evaluations.

7.2 Other information

The Chair informed that e-consultations concerning questions related to microorganisms can be launched within the Ad hoc WG MO. As opposed to what was said in the meeting, e-consultations will be launched by ECHA – based on proposals from MSCAs. The next Ad hoc WG MO meeting is provisionally planned for 8 September 2017 as a physical meeting because of the forthcoming discussion on the *Willaertia magna* CAR, but this will be confirmed in due time.

List of Attendees

Ad hoc Working Group Microorganisms

Members
BOSMAN-HOEFAKKER Saskia (NL)
BUSSCHERS Marloes (NL)
BOUBAKER Baia (FR)
OBIANG Esther (FR)
STRACZEK Anne (FR)
DIETERICH Frank (DE)
KEHRER Anja (DE)
SCHÄFER Anne (DE)
SIKORSKI Martha (DE)
FONNESBECH VOGEL Birte (DK)
HENRIKSSON Rebecca (SE)
NUTI Marco (IT)
PLANCHAMP Chantal (CH)
Advicers
CHEZEAU Aurélie

ECHA Staff
PRIHA Outi (Chair)
JANOSSY Judit
SZYMANKIEWICZ Katarzyna
SCHAKIR Yasmin
GLANS Lotta
ESTEVAN-MARTINEZ Carmen
AIRAKSINEN Antero