WGMO-4
Final minutes
26 June 2018

Minutes of Ad hoc Working Group Micro-organisms WGMO-4

22 May 2018

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 4th Ad hoc WG MO meeting. There were eleven members who participated in the meeting. In addition one rapporteur, four experts and one ASO expert (only for non-confidential agenda items) participated in the meeting. Applicant was registered for specific substance discussion.

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

There were no 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. The UK expert declared to have a conflict of interest regarding agenda item 5.1, and informed not to take part in the discussion of that item.

5. Discussion of active substances

5.1 *Bacillus thuringiensis* subsp. *kurstaki*, serotype 3a3b, strain ABTS-351 PT18 - post approval data (eCA FR)

There was one open point on provision of data for setting the reference specifications as indicated in the BPC opinion. The WG agreed to require further information from the applicant. An ad hoc follow-up will be launched.

6. Technical and guidance related issues

6.1 Update on guidance (ECHA)

The Chair informed that the first draft for guidance for technical equivalence (TE) assessment of micro-organisms, prepared by ECHA, is still on hold because of the ongoing update of the main guidance on TE assessment. Due to a large amount information for micro-organisms assessment being taken from the main guidance, it should be sufficiently advanced to enable progress with the micro-organisms part.

Cefic asked about the expected timeline for the main guidance on TE assessment, and SECR explained that the guidance is now in Partner Expert Group consultation, and is expected to be finalised during the second half of this year.

6.2 Continuous manufacturing process for micro-organisms (FR)

An e-consultation on continuous manufacturing process for micro-organisms had been launched on the initiative of FR, who presented the topics of the consultation. The questions posed to Ad hoc WG MO were:

1) What are definitions of different MS for the following terms:
   - "continuous manufacturing process" or "TGAI hypothetical stage" or "integrated process"

- "stability" for the technical active substance

2) What are the requirements of different MS for the characterisation of the commercial microbial active substance manufactured in continuous manufacturing process used as a biocide?

The e-consultation had been provided to Ad hoc WG MO members and Cefic, and comments had been received from DE, DK, FI and NL.

The WG discussed about whether definitions should and could be provided for the terms "continuous/integrated manufacturing process", "TGAI hypothetical stage" or "stability" of the technical active substance.

It was noted that in the BPR Vol V Guidance on Active Micro-organisms and Biocidal Products, ver 2.1 (BPR Vol V guidance for MO) the definition of TGAI is given, but the term "hypothetical stage" is not used. Concerning the terms "continuous/integrated process" and "stable" some members were in the opinion that the terms is question are dependent on the context in which they are used, and exact definitions cannot be given for them. Instead case-by-case decisions should be taken for the different processes. Some members, however, were in the opinion that definitions would be useful. FR proposal for defining "not stable" was discussed: *"Microbial active substance (MO AS) is not stable if the content of the MO AS (in CFU/g, ITU/g,…) in the hypothetical TGAI is lower that the content desired by the Applicant and/or the microbial contaminants are higher than the threshold limits indicated in the OECD 65 (Oct 2011). In this case, the continuous manufacturing process is performed."* Cefic was in the opinion that the continuous manufacturing process is not always dependent on the stability of the MO AS. Cefic further elaborated that continuous manufacturing process for micro-organisms differs from that for chemicals, and that for micro-organisms it is usually a question of how much water is present in different phases. Often for an integrated or continuous process the reason is that it would be economically unviable to do first a drying out process and then a re-wetting one.

Another issue brought up by Cefic concerned the requirement to provide minimum, maximum and nominal values for the content of the micro-organism. According to Cefic the content is needed both for risk assessment and efficacy, and for risk assessment it is rational to provide the content in colony forming units per gram, including maximum values. In contrast for biopotency, which is related to efficacy, minimal and nominal values corresponding to the label claims should be provided, but provision of maximum values would not make sense. Some WG members pointed out that when it is known that the micro-organism in question is not a pathogen and does not produce toxins or secondary metabolites, maximum values are not so important, whereas if toxic metabolites are produced, it is important to know the maximum count in the final product. It was noted that this issue was discussed at the PEG when the BPR Vol V guidance for MO was revised, and currently it is stated in the guidance that the minimum content of the MO AS has to be submitted, whereas maximum content needs to be reported only when concern exists of a risk to human health or environment due to exposure to the microbe, or if secondary toxins/metabolites are produced (see 3.1.1 section 2.7).

The WG also discussed the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products, and it was brought up that this paper is not a firm guideline, and that it is based on what is considered safe for food. SECR pointed out that this issue was brought up at the PEG discussion when BPR Vol V guidance for MO was revised, and in the current version it is stated that the OECD contaminant limits cannot be applied directly as such to biocidal products, and that the criteria and the suitability of methods should be judged on a case-by-case basis (see 3.1.2 section 2.3 and 3.2.1.3).

No new definitions or requirements were agreed upon, but it was concluded that the WG discussions will be recorded in the minutes, and that these issues may again be considered when more experience of MO assessment is gained. The Chair informed that in addition to WG minutes WG agreements of a general relevance can be recorded in the TAB (Technical Agreements on Biocides).

7. AOB

7.1 Other information and lessons learned

The Chair introduced briefly the status of on-going issues related to the work of Ad hoc WG MO. The WG has had discussions on whether nematodes should be in the scope of the BPR in an e-consultation and in a virtual meeting on 30 November 2017. The Ad hoc WG MO opinion on this issue has been sent to COM in March 2018.

The IUCLID team has prepared a TOC (Table of Contents) for microbial active substances, based on feedback received from the e-consultation to Ad hoc WG MO and from BPR IT user group meeting in November 2017. It is expected to be included in the next IUCLID 6 release in October 2018.

The next Ad hoc WG MO meeting is not decided yet. The Chair reminded that proposals for issues to be discussed can be sent to ECHA at any time.

List of Attendees

Ad hoc Working Group Microorganisms

Members
BOSMAN-HOEFAKKER Saskia (NL)
BOUBEKER Baïa (FR)
DIETERICH Frank (DE)
FONNESBECH VOGEL Birte (DK)
KEHRER Anja (DE)
KRÜGER Martin (DE)
LESLIE Wendy (UK)
NIEMINEN Timo (FI)
NUTI Marco (IT)
SCHÄFER Anne (DE)
STRACZEK Anne (FR)
Rapporteurs
GOUR Annabelle (FR)
Experts
CHEZEAU Aurélie (FR)
TESSIER Sonia (UK)
SIX Thérèse (FR)
ZIKOVA Andrea (DE)

ECHA Staff
PRIHA Outi (Chair)
GLANS Lotta
SZYMANKIEWICZ Katarzyna
Van de PLASSCHE Erik
SCHAKIR Yasmin
Applicants
Sumitomo/Valent-Biosciences
Stakeholders
MUNDAY Denise (Cefic expert only for non-confidential items)