Minutes of the Working Group meeting VI in 2018 for Analytical Methods and Physico-Chemical Properties

(Meeting date: 15 November 2018)

19 March 2019

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting which was held as a virtual meeting. CEFIC was registered as accredited stakeholder organisation (ASO) for this meeting with two persons.

The chair highlighted that only registered members can participate in this meeting although it is a virtual meeting, hence non-registered persons were requested to leave. Participants of the working group were informed that the meeting is recorded, but solely for the purpose of drafting the minutes and that the recording will be destroyed after the agreement of the minutes. The recording is not released to anybody outside ECHA and any further recording is not allowed.

2. Agreement of the agenda

The Chair introduced the draft agenda and invited the working group members to include any additional items under any other business (AoB).
The following items were added to the agenda:

- Participants and suppliers on the Article 95 list listed in the Summary Product Characteristic (SPC);
- Reports on the assessment of technical equivalence.

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

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None were declared by the working group members.

4. Agreement of the draft minutes of working group meeting V 2018

Comments on the draft minutes were received as follows:

Sulfur dioxide generated by combustion of sulfur: France

Sulfur dioxide released by sodium metabisulfite: France

General agenda items 10.5 Increase of relevant impurities after storage: France

The draft minutes have been updated accordingly and distributed with the meeting documents. The working group members agreed on the modifications. No comments on the other parts of the minutes have been received.

The minutes of the working group meeting V in 2018 have been agreed by the working group members.

5. E-consultations on scientific and technical issues

5.1. Shelf-life read-across

The open issues were discussed and agreed by the working group members.

5.2. Relevant impurities

The open issues were discussed and agreed by the working group members.

5.3. Technical equivalence assessment of active substances based on other legislations

The open issues were discussed and agreed by the working group members.

5.4. Ehtylene oxide – acceptance of data

The open issues were discussed and agreed by the working group members.

6. AOB

6.1. Use of updated FAO manual, version 2.0, 2018

The ECHA's Guidance on the BPR: Volume 1 Parts A+B+C (Version 2.0, May 2018) refers to the 2010 version of the FAO Manual.

However, the 2016 version of the FAO Manual is available which includes revised/new CIPAC methods.

Applicants are usually advised by the ECHA's Helpdesk to contact the MSCA responsible for the evaluation of their dossier for discussing whether the updated 2016 version of the FAO Manual is applicable.

The impact of the revised CIPAC methods on the results of the studies was not investigated yet, which could impact the choice on which version to follow. However, from initial considerations it seems that results will not be significantly impacted.

Working group members agreed to allow applicants to follow the 2016 FAO Manual including the updated CIPAC methods. However studies performed according to the 2010 version should still be accepted, as this is the one mentioned in the ECHA guidance.

The TAB will be updated mentioning that the version of 2016 FAO Manual can also be used, as an intermediate solution until the guidance will be updated.

6.2. Participants and suppliers on the Article 95 list

It was explained that suppliers listed in the article 95 list should not to be confused with reference sources of the active substance.

It was further clarified that only manufacturers (names and addresses of the manufacturing location) are reference sources when they are either listed in the reference specification document of the approved active substance, or for which a positive decision of the assessment of technical equivalence has been issued.

Alternative sources (of approved active substances) must apply for the assessment of technical equivalence. A positive decision of the assessment of technical equivalence should be included when submitting the authorisation application for biocidal prodcuts.

6.3. Technical equivalence decisions

The ECHA secretariat replied upon the request of a working group member, that indeed the technical equivalence decisions are uploaded in R4BP 3 already now. In the future ECHA will also include the internal report on the assessment of the technical equivalence assessment.

Annex 1 - List of attendees

Country	Members of WG
Austria	THANNER Gerhard
Belgium	VAN BERLO Boris
Denmark	SKOU CORDUA Birgitte
Estonia	ILMARINEN Kaja
Finland	KORKOLAINEN Tapio
Finland	KARPPANEN Essi
France	WEBER Philippe
Germany	MŰHLE Ulrike
Ireland	BROWN Finbar
Ireland	O'CONNOR Maire
Italy	CATALDI Lucilla
Norway	HELGERUD Trygve
Poland	HUSZAŁ Sylwester
Slovenia	ČEBAŠEK Petra
The Netherlands	HUIZING Tjaart-Jan
United Kingdom	WARBURTON Anthony

ECHA staff
KREBS Bernhard (Chair)
VIEIRA LISBOA Duarte
MATTHES Jochen
SCHAKIR Yasmin
AIRAKSINEN Sanna

Company	Observer
ERM	ELSMORE Richard
ERM	BYRAVAN Rama

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
Cefic	MIHAI Camelia
Cefic	KASURINEN Ossi

WG-VI-2018
Final minutes
22.1.2019

Minutes of Efficacy WG-VI-2018

14 November 2018 (WebEx)

Meeting of the Efficacy Working Group of the Biocidal Products Committee

PUBLIC

Efficacy Working Group

1. Welcome and apologies

The Chair welcomed all participants to the 24th Efficacy WG meeting. There were 4 core and 4 alternate members who participated in the meeting. In addition, 13 flexible members, 3 advisers, 1 ASO representative and 2 ASO experts attended the EFF WG 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. Agreement of the agenda

The Chair introduced the agenda items. The EFF WG members agreed on the proposed agenda.

3. 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. Agreement of the draft minutes from WG-V-2018

The Chair informed that no comments for the draft minutes of WG-V-2018 had been received. Therefore, the draft minutes version was agreed by the EFF WG without any changes.

5. Discussion of active substances[1]

5.1 Early WG discussion - Lactic Acid (eCA DE)

Please refer to the confidential draft minutes of this agenda item.

5.2 Early WG discussion - C(M)IT (eCA FR)

Please refer to the confidential draft minutes of this agenda item.

6. Discussion of Union authorisation applications

6.1 Early WG discussion - UA of PAA based disinfectants (eCA DE)

Please refer to the confidential draft minutes of this agenda item.

7. AOB

7.1 Relevant test bacteria for preservatives (DE)

Based on the discussion the EFF WG decided that:

1. Valid data proving efficacy against both:
   a. at least one Gram-negative, and
   b. one Gram-positive test organism

   with a total of at least four test organisms is required for a general antibacterial claim.
2. When mixed consortia (Gram-negative and Gram-positive bacteria in the same consortium) are used, data submitted on the consortium as a whole will be accepted.

[1] The details of the substance and UA application discussions are considered restricted. Only the non-restricted conclusions are reported here.

3. *Pseudomonas* spp. is a mandatory Gram negative test organism for liquid preservatives In case that, in an efficacy test, the chosen *Pseudomonas* species does not grow, but other test bacteria do (only relevant for single-species tests, but not consortia), this could be accepted if it can be justified that *Pseudomonas* is not relevant in that specific case, but the valid test organisms are.

7.2 (Non-)activity of acids in H_2O_2 formulation (FR) – closed session

Please refer to the confidential draft minutes of this agenda item.

7.3 Other information (ECHA)

The EFF WG members were informed about upcoming meetings.

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
ESCH Daniel (DE)
HAMEL Darka (HR)
POULIS Joan (NL)
Alternate members
GUNNEWIG Kathrin (DE)
MAXIMILIEN Yann (FR)
SMITH Ryan (UK)
WORM Petra (NL)
Flexible members
BALDASSARRI Lucilla (IT)
DAVIES Michael (UK)
FONNESBECH VOGEL Birte (DK)
ILMARINEN Kaja (EE)
HUSZAŁ Sylwester (PL)
KAUKONIEMI Sanna (FI)
LEPAGE Anne (BE)
McGee Conor (IE)
NIEMINEN Timo (FI)
PECINKOVA Martina (CZ)
PEELMAN Natania (BE)
ROSSIER Nadine (CH)
RYDMAN Elina (FI)
ZUTZ Christoph (AT)
Advisors
DONZE Gerard (CH)
KRUGER Martin (DE)
WIAK Joanna (PL)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
STASKO Jolanta
SCHAKIR Yasmin
Applicants
Corbion
Novadan
Thor
Stakeholders
ASHWORTH David – CEFIC expert
KASURINEN Ossi – CEFIC
THEELEN Meredith – AISE expert