WG-I-2021

Final minutes

8 June 2021

Minutes of Efficacy WG-I-2021

18, 23 and 25 March 2021

Meeting of the Efficacy Working Group of the Biocidal Products Committee

Efficacy Working Group

1. Welcome and apologies

The Chair welcomed all participants to the 35th Efficacy Working Group (EFF WG) meeting and informed that this meeting is split into three separate days.

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

2. Administrative issues

SECR gave brief information on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items. The EFF WG members agreed on the proposed agenda. SI asked for the possibility to introduce an ongoing e-consultations under AOB. The EFF WG 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 was declared.

5. Minutes

DE had sent comments on the EFF WG-IV-2020 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 18 March 2021

6.1. L-(+)-lactic acid (eCA DE)

There were no open points for discussion. The EFF WG agreed with the evaluation of the eCA.

7. Discussion of Union Authorisations – 18 March 2021

7.1. UA for product family containing Permethrin (eCA DK)

There were two open points and one provisionally closed point in the discussion table. The open points were closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

7.2. UA for product family containing Active chlorine released from chlorine (eCA BE)

There were three open points, which were all closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

7.3. UA for product family containing Active chlorine released from sodium hypochlorite (eCA BE)

There were no open points for discussion. The EFF WG agreed with the evaluation of the eCA.

7.4. Early WG on UA-APP containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide (eCA FR)

Please refer to the confidential minutes in the form of the discussion table for more details.

8. Technical and guidance related issues – 23 and 25 March 2021

8.1. Vol. II, Parts B+C – PT1-5

The BPR Guidance Vol II Parts B+C Efficacy – Assessment and Evaluation regarding disinfectants (PTs 1-5) sections had been revised in order to implement the agreements made for Appendix 3 on test organisms and Appendix 4 on Test requirements. The section for room disinfection in PT2 had been revised to align the requirements with the newly published EN 17272 standard, and new sections for room disinfection in PT3 and PT4 had been added. In addition, entries from the Technical Agreements on Biocides (TAB) concerning disinfectants had been implemented.

The major WG agreements are briefly summarised below:

Room disinfection/automated airborne disinfection of surfaces in PT2:

- The paragraph describing automated airborne systems was clarified and simplified;
- The detailed descriptions of the different diffusion types were removed, and it was agreed that the DE will send proposals for brief general descriptions;
- The average flow rate and average droplet diameter will be kept as parameters that need to be reported from the efficacy tests;
- The part "if a pre-cleaning step has been made" was replaced by "clean/dirty conditions" to be reported from the efficacy tests;
- The sentence extracted from EN 17272 standard describing the testing approach for claimed room sizes larger than 150 m^3 was clarified;
- The instructions for taking run-off into account in the efficacy testing were agreed to be moved from "Parameters to be included in the SPC" into "Test requirements";
- The requirement to give the flow rate in the SPC will be flagged for Partner Expert Group (PEG) discussion;
- Humidity will be kept as a parameter to be reported in the SPC, but it was amended into "humidity recommendation";
- It was agreed that biological/chemical validation should be a requirement rather than a recommendation in the SPC. The details of the validation were flagged for a PEG discussion.

Textile disinfection in PT 2

- "Textile disinfection" was amended into "Textile / Laundry process disinfection";
- Additional clarification on the test organisms and intended claims in different temperature regimes was added as follows:
    - ≥60 °C: Valid tests against *E. faecium* permits claims against bacteria, yeast, fungi and mycobacteria
    - 40 °C < T < 60 °C: All claimed groups of target organisms need to be tested. If test organisms from one group are not valid in the water control but reach a sufficient log reduction in the biocide sample, this target organism group can be claimed if valid tests with *E. faecium* have been submitted
- The requirement for testing the standard non-temperature resistant test organisms at the maximum validated temperature of phase 2, step 1 test was removed accordingly.

As the next step ECHA will update Vol II Parts B+C disinfectants section based on the agreements made. A PEG discussion of the revised guidance is foreseen for autumn 2021, and publication of the revised guidance for the beginning of 2022.

8.2. TAB proposals

PT14: Efficacy requirements for products with a lowered active substance concentration (DE)

The draft document prepared by DE concerned anticoagulant rodenticides containing the active substance at a concentration of 25-30 ppm. TAB amendment with new requirements for efficacy testing of such products was proposed. The EFF WG participants expressed

their concern related to the tested species (Rattus rattus) and a required mandatory field test for FGARs. It was pointed out that roof rats are not available everywhere in the field and therefore a semi-field trial should be allowed instead of a field trial, as is currently stated in the efficacy guidance. As a general note, it was also mentioned that the necessity of a laboratory test is doubtful. DE will revise the proposal, taking into account comments made, and send it to ECHA. The revised proposal will be circulated for comments before the next discussion at the EFF WG.

PT18: Crack and crevice treatment test (NL) – closed session

Please refer to the confidential minutes

8.3. Resistance assessment guidance of biocidal antimicrobial active substances and products (FR)

The first draft was prepared by FR and commented on by several member states, ECHA and ASOs. The discussion focused on the proposed tiered approach, whereas a first step a literature review was requested at the active substance approval and product authorisation stage. It was agreed that a literature review should be required only at the active substance approval stage.

The WG members had different opinions on requirements for laboratory and field tests. It was proposed that if a strong indication of risk for developing resistance is evident based on a literature review of the active substance, waiving the literature review and possibly even studies and focusing on establishing resistance management strategies should be possible at product authorisation.

It was pointed out that for some PTs the requirement for additional studies leads to an increase in animal testing. Also, the requirement for field trials raised some concern whether reliable data can be expected from such a study since the development of resistance sometimes is a long-lasting process. Monitoring data might be more accurate.

It was also noted that the definitions in the literature are not consistent, therefore definitions for important terms should be agreed upon within EFF WG and used for evaluation of the submitted data. The following terms should be defined: resistance, cross-resistance, co-resistance, adaptation/acclimation, tolerance and unacceptable.

Requirements for the literature review, e.g. the literature search parameters (number of databases, keywords, etc.) and qualified publications (journal, dissertations, date of publication, relevance of the data, etc.), were discussed. It was brought into attention that the ED guidance contains some general instructions for conducting a literature review that could be utilised when writing the instructions for resistance guidance.

These definitions will be drafted and discussed further within the newsgroup.

FR will revise a draft taking into account the received comments on the tiered approach and literature data. Relevant definitions will be included as well. Before the next discussion at the WG level, a Newsgroup in S-CIRCABC will be created to collect comments from the WG members.

8.4 Requirements for insecticide and repellent treated articles (SE)

SE gave a presentation concerning report and draft guidance on how to assess the efficacy of treated articles, and how to estimate exposure from them. It was underlined that there are still some aspects to be discussed, like washing, ironing, or drying and addressing this on the label. The draft will be further discussed, and it is flagged for a future update of the Vol. II, Parts B+C.

9. AOB

9.1. Other information & lessons learned

ECHA informed about provisional dates of the next WG meeting. It was pointed out that due to very limited time given in PF40 for individual phases and expected a high number of dossiers EFF WG meeting is limited to discussions only on AS and UA cases. All UA

discussions will take place during the second week of the WGs meeting. In addition, the Chair kindly asked the commenting MSs to avoid comments like '*nice to have*' as time for DTs preparation and discussions at the WG may be limited. Moreover, short information about current guidance updates and foreseen future discussions was given. A clarification was given by ECHA with reference to e-consultations and early WG discussions. It was noted that the members from different WGs and different MSs have different understandings of what these tools are intended for. ECHA clarified the concepts indicating that an e-consultation should be understood as a measure where a MS seeks advice from (other) experts. The outcome of an e-consultation is advice, not a conclusion, and if needed, the MS can seek a WG discussion. In an early WG discussion, conclusions are possible within the WG mandate. The conclusions should however be provisional if the final conclusion requires seeing the complete assessment, e.g. whether the data package is complete, or if general discussions are ongoing, e.g. guidance is under development, or if a policy/regulatory decision is needed and/or the discussion is ongoing, e.g. at CA or CG level. ECHA noted that for all these cases, the WG can make case-specific conclusions in a regular WG discussion but not in an early WG meeting. A usual e-consultation review was presented, initiating MSs were asked for a summary of the finalised items to be uploaded on S-CIRCABC.

9.2. Meeting the timelines: alternative ways of working - closed session

Please refer to the confidential minutes.

List of Attendees

Efficacy Working Group I-2021

Core members
ZUTZ Christoph (AT)
JANSEN Irina (DE)
KRÜGER Martin (DE) - alternate
ATTIG Isabelle (FR)
MAXIMILIEN Yann (FR) - alternate
POULIS Joan (NL)
DUH Darja (SI)
Flexible members
BURMISTROVA Anastasia (BE)
DANG THY Minh-Dung (BE)
LEPAGE Anne (BE)
DONZE Gerard (CH)
GRÜNIG David (CH)
MEIER Margrith (CH)
WANDELER Eliane (CH)
DOLEZELOVA Katsiaryna (CZ)
PECINKOVA Martina (CZ)
BANDOLY Michele (DE)
TRAUER-KIZILELMA Ute (DE)
CLEYTON JØRGENSEN Charlotte (DK)
FONNESBECH VOGEL Birte (DK)
PLOOMPUU Grethe-Johanna (EE)
NIEMINEN Timo (FI)
RYDMAN Elina (FI)
BILLAULT Catharine (FR)
HADDACHE Nabila (FR)
LYNCH Helen (IE)
OWENS Aoife (IE)
BALDASSARRI Lucilla (IT)
RONCI Maria Beatrice (IT)
MEZULE Linda (LV)
WARMERDAM Sonja (Nl)
WIGGERS Hanneke (NL)

AAMODT Solveig (NO)
HUSZAŁ Sylwester (PL)
JUSZCZUK Marek (PL)
DAN Marius (RO)
FRANK Ulrike (SE)
MALMGREN Birgitta (SE)
ÅSLING Bengt (SE)
DANADAIOVA Emese (SK)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
RAULIO Mari
SCHAKIR Yasmin
HONKA Anni
Applicants
Agrobiothers
ARCHE
Christiansen SARL
Procter & Gamble
Purac Biochem
Rapporteur
LEROY Celine (FR)
Advisor
DEKKERS Bas (NL)
GEDUHN Anke (DE)
KASPRZAK Karolina (PL)
SOUMET Christophe (FR)
Stakeholders
GARMENDIA Irantzu (EBPF)
BERNARD Jennifer (expert)
STEINHAUER Katrin (expert)
MORENO Mara (expert/AISE)
THEELEN Meredith (expert/AISE)