Human Health WG-III-2018

FINAL minutes

18 September 2018

Minutes of Human Health WG-III-2018

29-30 May 2018

Meeting of the Human Health Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 32 members registered, of which 9 were core members. One stakeholder expert was present for non-confidential agenda items. Applicants were registered for their specific substance discussions.

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 presentation on housekeeping and administrative issues.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The agenda was agreed without changes.

4. 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.

5. Discussion of active substances

5.1 Early WG discussion on monochloramines generated in situ (eCAs: AT, UK, FR, SE)

The discussion mainly concerned the available data package, waiving of studies and the need to require further information. The WG agreed that some new studies will be necessary for some endpoints, while further considerations will be necessary for other endpoints. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

5.2 Prallethrin (eCA EL)

Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6. Technical and guidance related issues

6.1 Update on guidance development

SECR presented the current status of several guidance-related documents which are at different stages of development, including general documents as well as those developed in the context of the ad hoc Working Groups on Human Exposure (HEAdhoc) and Assessment of Residue Transfer to Food (ARTFood). The identified needs for further guidance development were also presented. The document is available in S-CIRCABC to members and associated stakeholder organisations.

6.2 Relevant impurities

In addition to the Human Health WG, several members of the Environment WG and APCP WG participated in this discussion, as the issue is also relevant for them.

SECR introduced the document and asked for initial feedback on the proposal, explaining that based on the discussion, a revised version of the document will be provided for commenting. The comments made during the discussion mostly concerned details that would need to be clarified and/or amended.

Condition 1. It was suggested to remove endocrine disruptors, POP and PBT from the examples and reconsider referring to exclusion criteria and SVHC.

Condition 2. It needs to be clarified how to select the correct classification for impurities when harmonised classification is not available, as this would usually be the case. One member questioned applying the threshold of 10 % of the CLP classification limit for relevant impurities, noting that products with e.g. category 2 mutagens would not be classified below 1 %. Clarification that the approach is based on FAO would be needed.

Condition 3. The reliability of the NOAELs used for impurities will need to be addressed, as well as the question on which NOAEL (e.g. duration) of the active substance should the value be compared with. SECR noted that the new ECHA Guidance on Technical Equivalence (to be published later this year) contains useful information for this purpose.

Condition 4. The condition will be clarified to indicate more clearly in which cases this condition is applicable and when it is necessary to perform the QSAR analysis. The wording regarding "impurities of unknown toxicity" will also be clarified/amended. One member commented that many impurities will be variations of the active substance and for these the toxicity might not really be unknown.

It was noted that harmonisation with pesticides would be important. SECR informed that input is expected from EFSA on the current document and this input will be taken into account in revising the document. SECR interpreted the initial EFSA feedback to be overall supportive of the approach.

The increase in an impurity concentration allowed in the technical equivalence (TE) guidance was discussed. SECR clarified that the allowed increases specified in the guidance concern only significant (above 1 g/kg) and not relevant impurities, and the maximal increase for significant impurities is four-fold, from 1 g/kg to 4 g/kg. The proposed (arbitrary) 10-fold factor in conditions 2 and 3 will thus protect from e.g. additional classification already in Tier I of the TE assessment. An impurity that is neither significant (i.e. below 1 g/kg) nor relevant would be considered as a new impurity in the TE assessment.

One member reflected that the document assumes all impurities to be known, which might not be the case. The applicant will make a decision in selecting which impurities to analyse, and not all impurities present below 1 g/kg will be known. The analysis has to cover significant and relevant impurities, and the definition of a relevant impurity will affect what is analysed.

The additivity of the effects of the impurities would also need to be addressed; this was identified as an item for further reflection. One member remarked that in an EMA draft guidance, the sum of the concentrations of impurities with the same genotoxic mode of action should not exceed the TTC.

The members generally supported the document and the approach. SECR will prepare a revised draft and will launch a commenting period.

7. Any other business

7.1 Other information & lessons learned

The presentation is available in S-CIRCABC to MSCAs and to associated stakeholder organisations.

Template for reference value information

SECR reminded of the agreement at WG-V-2016 that the eCAs should provide a document on human health reference values and absorption values. It would be most helpful if the document could be provided together with the CAR or with the RCOM, but it should be submitted at the latest together with the updated RCOM (step 15 of working procedure).

This document should be provided by filling in Chapters C.1.1 and C.1.2 of the new CAR template.

Endocrine disruptors (ED)

The guidance on ED assessment is expected to be published 7 June 2018, which is the date when the ED criteria become applicable for biocides.

For each biocidal active substance, it is now necessary to conclude "whether the substance should be considered to have ED properties or not to have ED properties" (CA-March18.Doc.7.3.a- Final), the only exception being if the eCA proposes clear non-approval (agreed at BPC-25[1]).

ECHA will organise a webinar on 19 June 2018 on the guidance, the criteria and the consequences for biocides.

The following ED EG meetings in 2018 will be 9-10 October and 8-9 November.

Next WG meetings

The timing of the next Human Health WG meetings is provisionally planned as follows:

- 4 July 2018 – virtual meeting
- 17-21 September 2018 – physical meeting, exact dates to be confirmed

1 https://echa.europa.eu/documents/10162/4221979/principles_ed_assessment_in_approval_active_substance_process_en.pdf

Annex 1

Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
ARAPAKI Niki (EL)
NIKOLOPOULOU Dimitra (EL) - Rapporteur
MAXIMILIEN Elisabeth (FR)
LORI Julia (FR)
HOLTHENRICH Dagmar (DE)
SCHUMACHER David (DE)
WELTEN Angelique (NL) Al
BRESCIA Susy (UK)
Flexible members
HAUZENBERGER Ingrid (AT)
HÖLZL Christine (AT)
TORDOIR Charlotte (BE)
HOUAMED Anis (BE)
ROSSIER Nadine (CH)
BÜHLER Dominique Anne (CH)
STRAUCH Stefanie (CH)
SUMBEROVA Hana (CZ)
PETERSEN Annika Boye (DK)
SCHMIDT Marianne (DK)
HYVÄRINEN Tuija (FI)
RYDMAN Elina (FI)
HÄMÄLÄINEN Anna-Maija (FI)
PUPIER Cindy (FR)
REY Marion (FR)
BREEN Alan (IE)
LÅSTBOM Lena (SE)

ECHA Staff
AIRAKSINEN Antero (Chair)
ANTAL Diana
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
MYÖHÄNEN Kirsi
PAPADAKI Lina
RUGGERI Laura
SCHAKIR Yasmin
Applicants
Sumitomo
Endura/EXEO-Consulting
ARCHE Consulting
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Buckman Laboratories NV
API-Additives for Paper Industry GmbH
Foxyde
Stakeholders
COREA Namali (CEFIC – expert)
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GRAVEN Coen (NL)
HERRMANN Kristin (DE)
PEISER Matthias (DE)