Environment WG-I-2014

Final minutes

20 April 2014

Minutes of Environment WG-I-2014

30 January 2014

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 6 core members and 2 alternate core members present in addition to 3 flexible members, 2 advisers and 2 rapporteurs. Three accredited stakeholder organisations (ASOs) were present at the meeting. Applicants were also present 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. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The following additional items to the agenda were proposed:

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.

4. Administrative issues

4.1. Housekeeping issues

The key aspects of the housekeeping rules including the safety and security rules were presented.

5. Discussion of active substances[1]

5.1 Alpha cypermethrin

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

5.2 Folpet

All points were agreed by the WG. The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

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

6. Technical and guidance related issues

6.1 Mesocosm guidance

Please refer to Appendix 1: Discussion table – Item 6.1

Conclusions and actions

The guidance was agreed by the WG.

Actions required after WG-I-2014:

- NL to send text-/editorial changes as discussed in WG-I-2014.
- ECHA to include the mesocosm guidance into Vol. IV Part B.

6.2 2nd EU Leaching workshop on wood preservative – result of the e-consultation on open issues

Please refer to Appendix 2: Discussion table – Item 6.2

Conclusions and actions

Points 1 and 2 have been closed, the conclusions are provided in the discussion table (see Appendix 2).

Actions required after WG-I-2014:

- The conclusions are to be sent to the CA meeting
- Request for discussion of the protection goal (open point 3) will be send to the Ad Hoc Environmental Exposure WG.

6.3 Update on guidance development

The Chair presented the status on guidance development (please refer to Appendix 3 below). Concerning the guidance document on mixture ecotoxicity assessment within biocidal products authorisation it was agreed that the finalised document will be published on a holding page until the Vol. IV part B (for the product) is prepared, in which it will be included.

7. Any other business

None.

List of Attendees

Core members
LEFÈBVRE Frederic (BE)
KOIVISTO Sanna (FI)
ALEXANDRE Stéphanie (FR)
CHION Béatrice (FR)
KEHRER Anja (DE)
OKKERMAN Peter (NL)
Alternate core members
AHTING Maren (DE)
PACHITI Irene (GR)
Flexible members
CHRISTENSEN Anne Munch (DK)
KRYSZCZUK Artur (PL)
HAHLBECK Edda (SE)
Rapporteurs
BRANDT Charlotte (BE)
FANELLI Roberto (IT)
Advisers
KAUKONIEMI Sanna (FI)
SMIT Els (NL)

ECHA Staff
SCHIMMELPFENNIG Heike (Chair)
SAEZ RIBAS Monica
BARMAZ Stefania
FABREGA CLIMENT Julia
ASO Observers
LEROY Didier (CEPE)
GRAY Adrian (CEPE)
BAIRD Gilly (PISC)
Applicants
AZMON Adi (Makhteshim Agan Group)
Steve Norman (Expert for A. Azmon)
NIGGEWEG Ricarda (BASF SE)
HABEKOST Maike (Expert for R. Niggeweg)

Appendices:

Appendix 1: Agenda item 6.1: Mesocosm guidance

Background

The guidance document for the use of aquatic model ecosystem studies for biocides (mesocosm guidance) was presented and discussed at TM IV 2013 (agenda item 3h). Following the request of some member states, an additional commenting period was added. Comments received are summarised in the discussion table below.

Meeting date: 30 January 2014

Discussion table – Mesocosm guidance

a) No.	b) Issue and background Ref. in guidance document	c) WG discussion/ Ad hoc follow-up where relevant	d) Open/closed point Conclusions	e) Action points Deadlines
1	Should a new decision scheme depicting the different assessment steps replace Figure 3. Section 3.1.1.Introduction One MS suggests to replace the current Figure 3 with their propose scheme (Page 7).	It was proposed and agreed to include both figures in the text. The references will be updated referring to the correct sections. No further discussion took place.	Point closed/ It was concluded that both figures should remain in the guidance.	
2	When the recovery option is considered for the risk assessment, is the text sufficiently clear to prevent a misinterpretation of the type of sensitive taxa that is needed in the mesocosm study? Section 3.1.2. Representative aquatic community One MS stated that the text should be refined to indicate that the point is not that *sensitive* univoltine species are missing, but that sensitive *univoltine* species are missing and sensitive bi- or multivoltine species are present. The current cited EFSA text (Line 235) may lead to misinterpreting that missing sensitive univoltine species would lead to a too high NOEC (Page 8, Line 223).	It was agreed that the clarification was necessary. It was proposed to include the paragraph in a different part of the section, for a clearer understanding. No further discussion took place.	Point closed/ It was concluded that additions are accepted, the text will be reformatted as indicated to improve readability.	
3	Is it necessary to include a more precise guidance on the expected exposure patterns for biocide	It was suggested to develop a more precise guidance on the expected exposure patterns for different product types.	Point closed/ Proposal of the	

Meeting date: 30 January 2014

Discussion table – Mesocosm guidance

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	product types, in order to ensure that the exposure type in the mesocosm study is representative for the biocide product use? Section 3.1.3 Exposure One MS noted that it is not sufficient to state that for certain PTs the emission is potentially not continuous. E.g. for the PT 18 substances Imidacloprid,and Clothianidin it was agreed at TM level that mesocosm studies from the PPP-area with single peak exposures are not representative for the exposure from the use as biocide.	There might be exceptions that do not fit the exposure pattern of Table 1. New text will be included in Table 1 and a clear reference to Appendix 1, to indicate that for certain product types the evaluation of the exposure type has to be evaluated case-by-case. NL volunteered to provide new text for this section. No further discussion took place.	commenting MS was accepted. Reference to Annex I to be added.	
4	For consistency with other regulations, should the existing EFSA's table replace the current table 2- "Definition of endpoints of mesocosm studies", and new text on statistical power and Minimum Detectable Differences be included in the guidance? 3 Section 3.1.4 Evaluation and acceptability of recovery One MS proposed to use EFSA's table for reasons of consistency. Since EFSAs table includes information on the Minimum Detectable Difference (MDD) some explanatory lines are needed above the table. (Page 11, line 318)	The proposal was agreed. It was suggested that at a later stage the endpoints mentioned in the table should be carefully evaluated to see whether they are all relevant for biocides. No further discussion took place.	Point closed/ It was concluded that the table is to be included. It should be evaluated later if the endpoints to define the effect classes are applicable for biocides.	
5	Is it necessary to clarify that when metabolites are stable these have to be analysed in the study and included in the risk assessment? Section 3.2 Design of new studies	There was an initial discussion on what sort of metabolites would need to be identified and considered for the purpose of a risk assessment. It was agreed that the text already indicated that only those	Point closed/ It was concluded that relevant metabolites should be assessed if new studies are	

Meeting date: 30 January 2014

Discussion table – Mesocosm guidance

a) No.	b) Issue and background Ref. in guidance document	c) WG discussion/ Ad hoc follow-up where relevant	d) Open/closed point Conclusions	e) Action points Deadlines
	One MS stated that if a higher tier study is commissioned and relevant metabolites have been identified in fate and behaviour studies these metabolites should be measured in order to include them in the RA. (Page 15, Line 421)	'**relevant**' (e.g., persistent, toxic, etc) metabolites would need to be included in the analysis and test design of a commissioned biocide study.	commissioned.	
6	Should exposure scenarios be defined for specific PTs, in order to ensure that if the data from a mesocosm study using a single peak exposure is used, this is representative to the biocide? Section 3.3.1 Single peak exposure One MS suggested to include a clear definition of the term non-continuous exposure (which exposure scenarios for which TPs). In addition, it has to be carefully checked, whether the exposure of a mesocosm study has been long enough to consider the study relevant for the derivation of the PNEC for long-term exposure (Page 17, Line 489).	*This point was not discussed at WG-I-2014 since it was obsolete after trilateral discussions before the WG meeting.*		
7	Is it necessary that for non-continuous release biocides, it is highlighted in the text that if the initial concentration is used for the effects assessment, the PNEC should be compared with the PECinitial? Section 3.3.1 Single peak exposure One MS suggested that this issue is emphasized.	No discussion took place since there was a common agreement on this point.	Point closed/ The proposal was accepted.	
8	Is a single peak exposure study in which the tests substance concentration has declined considerably (80% decline) within the time window relating to the duration of the test, representative for the assessment of a biocidal product with continuous	No discussion took place since there was a common agreement on this point.	Point closed/ It was concluded that the example will be included in guidance, the place to be defined (annex versus	

Meeting date: 30 January 2014

Discussion table – Mesocosm guidance

a) No.	b) Issue and background Ref. in guidance document	c) WG discussion/ Ad hoc follow-up where relevant	d) Open/closed point Conclusions	e) Action points Deadlines
	exposure? Section 3.3.1 Single peak exposure One MS stated that a study with a single peak exposure and a dramatic decline in the tests substance concentration, as described, is not representative for the assessment of a biocidal product with continuous exposure, and might not be considered relevant for the derivation of the PNEC for long term exposure. (Page 18, Line 494-504)		guidance text).	
9	Should the text emphasize that using a mesocosm study for sediment assessment could be done (amongst the other conditions cited in the text), only for substances that are transferred to the sediment, and when the concentration of the substance in the sediment has been analysed and the sediment community is well represented in the study? Section 3.3.1 Single peak exposure One MS stated that using a single peak study for substances that dissipate fast and have a high ACR ratio, can only be used for the sediment assessment of the substance when the concentration has been measured in the sediments and benthic organisms have been present in the system in a sufficient number.	No discussion took place since there was a common agreement on this point.	Point closed/ It was concluded that the respective explanation is already there but it will be emphasised for clarification.	
10	As in comment No. 8: Is a repeated peak exposure study in which the tests substance concentration has declined considerably (80% decline) within the time window relating to the duration of the test,	No discussion took place since there was a common agreement on this point.	Point closed/ It was concluded that this point is covered by point 8 (i.e. providing the	

Meeting date: 30 January 2014

Discussion table – Mesocosm guidance

a) No.	b) Issue and background Ref. in guidance document	c) WG discussion/ Ad hoc follow-up where relevant	d) Open/closed point Conclusions	e) Action points Deadlines
	representative for the assessment of a biocidal product with continuous exposure? Section 3.3.2. Repeated peak exposure One MS stated that as indicated for single peak exposure mesocosm studies, a study with a repeated peak exposure and a dramatic decline in the tests substance concentration, as described, is not representative for the assessment of a biocidal product with continuous exposure, and might not be considered relevant for the derivation of the PNEC for long term exposure.		examples)	
11	Is it necessary that the text mentions that although a number of models exist that can provide information on the fate, behaviour and (eco)toxicological profile of the substance, their use for regulatory purposes is not yet clarified? Section 3.3.2. Repeated peak exposure One MS stated it should be mentioned that the use of modelling approaches for regulatory purposes has not yet been worked out in guidance, and an EFSA opinion on the use of mechanistic modelling approaches is expected for 2016 (EFSA, 2013).	It was agreed to only include in the text that EFSA is preparing an opinion on this issue, which should be available in 2016.	Point closed/ It was concluded that there will be only a sentence included that EFSA is working on an opinion. A reference to the related workshop will be included.	
12	Is there a need to specify that if the ecological recovery option is chosen, care should be taken to investigate whether the species in the mesocosm have adequate sensitivities? Section 3.3.2. Repeated peak exposure One MS stated that for repeated peak exposures, it is important to consider the toxicological	No discussion took place since there was a common agreement on this point.	Point closed/ It was concluded that the editorial addition, in line with the proposal of the commenting MS will be done.	

Meeting date: 30 January 2014

Discussion table – Mesocosm guidance

a) No.	b) Issue and background Ref. in guidance document	c) WG discussion/ Ad hoc follow-up where relevant	d) Open/closed point Conclusions	e) Action points Deadlines
	dependency of these pulses for the life span of the individuals of the sensitive species: If recovery is considered ecological independence (peak intervals are greater than the relevant recovery time of the sensitive populations of concern) has to be evaluated (EFSA, 2013).			
13	<u>Should this section include a clear reference to when a TWA approach is appropriate for the exposure and effects assessment?</u> Section 3.3.3 Continuous exposure One MS stated it is an important point to note as it is not stating that you can use a time weighted average PEC (as described in chapter 4.5 of EFSA 2013 'Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge of field surface water'). Whilst the use of a time weighted average approach may be appropriate in some circumstances it always needs to be considered if it is scientifically valid and supported by sufficient evidence to show reciprocity of effects at relevant concentrations and exposure durations.	No discussion took place since there was a common agreement on this point.	Point closed/ A reference to the respective paragraph in Vol. IV Part B will be included.	
14	<u>Should the factors that could be considered for lowering the RA be revised and/or made more specific?</u> Section 3.4. Application of an assessment factor to derive the $PNEC_{aquatic}$ **DE*:*** isn't it always the case that "a sufficient pre-treatment period has been included to allow the community to be well-established in the system"?	One of the criteria given by EFSA for choosing a low AF when a range is proposed, is to have a sufficient pre-treatment period to allow the community to be well-established in the system. It was unanimously considered as a requisite for any mesocosm study. It was agreed to keep this bullet point in the text but to further indicate that this had to be the case for all studies.	Point closed/ The point will be kept in the text since it is in line with EFSA guidance but a remark will be included that a pre-treatment is always needed.	

Meeting date: 30 January 2014

Discussion table – Mesocosm guidance

a) No.	b) Issue and background Ref. in guidance document	c) WG discussion/ Ad hoc follow-up where relevant	d) Open/closed point Conclusions	e) Action points Deadlines
15	<u>Is there a need to modify the AF discussed during the workshop?</u> In the workshop on Mesocosm biocide guidance held in Arona on 18 September 2013, AF to be applied on endpoints from mesocosm studies were discussed. Following the workshop, comments were submitted by several MS on the assessment factors and proposed single value AFs to replace the AF ranges.	The proposal for having a range of AF vs no-range of AF based on the type of mesocosm study available was discussed. It was the opinion of several MS that an AF of 10 would be too conservative for a mesocosm study given that this AF is already possible for laboratory data on 3 species from 3 different trophic levels. It was also agreed that the criteria for choosing an AF should not consider the exposure type, given that this is already an exclusion criteria in the guidance (when a mesocosm study could not be used). It was agreed to accept the revised proposal of the authors of the guidance. It was also discussed how data could be used when coming from different mesocosm studies. The following points were made: i) consider the lowest LC50/NOEC value to derive the PNEC, ii) To use the higher value (LO50/NOEC) if the decision was reasoned (case-by-case decision) and based on expert judgement (e.g., quality of the study) It was agreed that the choice of the value to use for the hazard assessment should depend on the information available, such as the quality of the data. The geographic effects that a study can have on the data obtained was discussed. However, it was the opinion of many MS that it was the species composition of the mesocosm study (i.e., that all relevant trophic levels were represented), more that the geographic location of the study and the species on it (e.g. temperature, salinity, etc.) which would determine the quality of the study and relevance of the data obtained.	Point closed/ It was concluded that the proposal prepared will be included. The explanatory text on the AF of 2 will be adapted to emphasise the need of at least two mesocosm studies. It was further concluded that if two studies are available the choice of the endpoint will be based on expert judgement.	

Appendix 2:

Agenda item 6.2: 2nd EU Leaching Workshop on wood preservatives - result of the e-consultation on open issues

Background

The 2nd EU Leaching Workshop took place in Varese, Italy on 12 June 2013. The conclusions of the 2nd EU Leaching Workshop have been distributed after TM II 2013 for commenting and the conclusions have been discussed at TM III 2013 on 20 September 2013.

Following the discussion at TM III 2013, an e-consultation was initiated in order to close remaining open points. The comments received during the e-consultation are briefly summarised in column c) below.

WG Environment – Item 6.2

Discussion table –2nd EU Leaching workshop on wood preservative – result of the e-consultation on open issues			Meeting date: 30 January 2014	
a) No.	**b) Issue (of the e-consultation)**	**c) Summary of responses of e-consultation (1) and WG discussion (2)**	**d) Open/closed point Conclusions**	**e) Action points Deadlines**
1.	Is the assumption of 50% leaching during Time 1 (= 30 days) acceptable as screening step for assessing the need of a leaching test?	A table document was presented summarising the evaluation of leaching data provided by several member states following a discussion at TM IV 2013. The table document shows the %-leaching for 4 active substances after 30 days and 365 based on semi-field tests and the %-leaching for 10 active substances after 30 days based on laboratory tests. The evaluation was performed in order to define a default value for the %-leaching for time 1 and based on the table document a default value of 20% was firstly proposed. It was questioned by some member states how reliable the database is in order to cover all active substances in PT 8, therefore a more conservative approach (i.e. 50% leaching during time 1) was preferred. It was further proposed that 100% leaching for T1 is still required for curative treatments (since these are not designed for fixation) and in-can preservatives, which was accepted.	Point closed/ It was concluded that 50% leaching during time should be assumed as screening step for assessing the need of a leaching test for preventive treatment.	

Discussion table –2nd EU Leaching workshop on wood preservative – result of the e-consultation on open issues			Meeting date: 30 January 2014	
a) No.	**b) Issue (of the e-consultation)**	**c) Summary of responses of e-consultation (1) and WG discussion (2)**	**d) Open/closed point Conclusions**	**e) Action points Deadlines**
2.	Should Time 1 be re-defined and how should it be dealt with if a risk is identified for Time 1 during product authorisation?	It was discussed if a second time point should be added in order to cover the time between application and end of service life. One MS proposed 180 day (covering one growing season). In addition 365 days were proposed in order to take into account all seasons of a year and because semi field test usually cover one (rain-)year. It was further discussed how to calculate the leaching rate. It was stated that if the default value of 50% leaching during time 1 is not fulfilled (see point 1), then anyway leaching data would need to be provided and the leaching could be calculated based on the results of the leaching test. If considering a default value of 50% leaching at time 1 (see point 1) does not show a risk, the second time would not need to be calculated and no leaching data are required. It was further proposed, following a comment from a member states on the additional workload for calculating a third time, to provide respective calculation sheets in order to facilitate the work for member states.	Point closed/ It was concluded to propose the following time scheme: Time 1: 30 days Time 2: 365 days Time 3: service life. If the scheme will be adopted, ECHA will provide a calculation template (e.g. Excel sheet) to reduce the additional workload for the member states.	To be sent to the CA meeting for adoption.
3.	How should the protection goal be defined for PT 8 substances?	This point was only very briefly discussed, it was sent to the future Ad Hoc Environmental Exposure WG for further discussion.	Open point	To be sent to the Ad Hoc Environmental Exposure WG once established.

Appendix 3:

Agenda item 6.3: Update on the status of ESD, guidance documents and on-going projects

Title (current leader)	Status	Place of publication
PT21 Env. Risk Assessment documents (UK)	Presentation and discussion at TM II 2013, endorsement at TM III 2013.	ECHA – ESD specific webpage
Regional marina scenario for PT 21 (CEPE/JRC)	E-consultation on cover note finished in October. Bilateral consultation DK-CEPE until end October 2013.	ECHA – ESD specific webpage
Scenario for freshwater marinas (NL)	Intention for scenario preparation presented at TM IV 2013. NL has started discussion with IND. First draft potentially available towards Q4 2014.	ECHA – ESD specific webpage
Cut off criteria for groundwater assessment of biocides (UK)	Endorsed at TM IV 2013. CTGB raised some possible limitations. UK to follow up (single versus continuous emissions, metabolite leaching). Final version scheduled for endorsement for **WG-II-2014**.	Recommendation or holding page for Vol IV part B (first revision) - tbc
Leaching to groundwater from paint, coatings and plaster (NL)	Trilateral discussions (NL, DE, UK) to be initiated, draft likely to be discussed at **WG-II-2014.**	ECHA – ESD specific webpage
Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments (DE)	Finalisation of draft by mid-2014 - to be clarified.	Vol IV part B (first revision)
Evaluation of the model SimpleTreat (DE)	Finalised at TM level.	Vol IV part B or recommendation - tbc
ESD PT13-Use of the OECD Guidance (IND/NL)	Questionnaire and data gathering during Oct./Dec. 2013 – status is open.	ECHA – ESD specific webpage
Scenario for the biocidal use and emissions from oil platforms PT11/ PT12 for PEC calculations (NL)	Presentation of intention at TM IV 2013, draft potentially available for **WG-II-2014**, NL to confirm by end of February.	ECHA – ESD specific webpage
Direct emissions to surface waters in PT 6, 7, 8, 9 and 10 (DE)	Discussed at TM II 2013, followed by a commenting period – status is open.	ECHA – ESD specific webpage
Use scenarios for PT09 roof membranes	Presentation at TM IV 2013 – status is open.	ECHA – ESD specific webpage
Environment Substances of Concern (SoC) (UK/DK/DG ENV)	UK is awaiting worked examples from DK in order to compare proposals with the scheme prepared by DK. UK to continue development. COM in charge (via CG), WG may be consulted for technical issues.	Vol IV part A ENV, part C ENV
Guidance document on mixture ecotoxicity assessment within biocidal products authorisation (DE, ECHA)	Document is finalised, will be published for the time being on its own on a holding page before inclusion in Vol IV part B (product)**.** ***The proposed procedure was confirmed by the Environment Working group during WG-I-2014. There was a common agreement on this point, no further discussions took place.***	Vol IV part B (product)

Title (current leader)	Status	Place of publication
Guidance document on higher tier strategies and evaluation of PPP data endpoint for biocides risk assessment (IND/NL)	Following a commenting period discussed at **WG-I-2014**.	Vol IV part B
2nd EU Leaching Workshop for PT 08 (DE, ECHA)	Open points were discussed at **WG-I-2014.**	ECHA – ESD specific webpage
Fish net scenario in aquaculture (NO)	E-consultation planned to be started in February.	ECHA – ESD specific webpage
Guidance documents on risk mitigation measures for PT 1-5 (DE)	In public consultation ending 26/02/2014, follow-up to be clarified.	Vol IV part C (holding page)
PT6-10 city scenario (NL)	Endorsed TM III 2013.	ECHA – ESD specific webpage