Final minutes of the Working Group meeting II in 2018 for Analytical Methods and Physico-Chemical Properties

(Meeting date: 17 April 2018)

03 July 2018

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. No accredited stakeholder organisation (ASO) was present at this meeting.

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. Administrative issue

A presentation on the administrative matters was provided by ECHA for information.

3. 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:

- Post approval data for silicon dioxide.
- Analytical methods for biocidal products that have been deemed not necessary for the approval of the active substance.

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 by the working group members.

5. Agreement of the draft minutes of working group meetings V 2017, VI 2017 and I 2018

Comments on the draft minutes were received as follows:

Working group meeting V 2017

Salicylic acid: The Netherlands

DDAC: Italy

ADBAC/BKC: Italy

General agenda items: Italy

Working group meeting VI 2017

No comments received

Working group meeting I 2018

Active chlorine: Italy

General agenda items: 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 meetings V and VI in 2017 and I in 2018 have been agreed by the working group members.

6. Follow up of previous working group meetings and e-consultations

6.1 Open issues of previous working group meetings

ECHA provided an overview on open issues/ requested information that should have been provided by the applicants to the eCAs and for which the deadlines are exceeded. A table with these items will be sent to each concerned member state.

6.2 Outcome of e-consultations

- **Chlorfenapyr**

  The applicant provided new 5-batch analyses that have been used to update the reference specification. The working group members could not agree on the proposed references specification and requested additional time for verifying the proposal. Therefore an e-consultation will be initiated for agreement. No further discussion at future working group meeting is expected.

- **Silver zinc zeolite**

  The chair presented an overview of the outcome of the e-consultation. All open points have been addressed by the comments received during e-consultation, no further discussion took place at the working group meeting.

- **d-Allethrin and Esbiothrin**

  The chair presented an overview of the outcome of the e-consultation. The eCA still needs to finalise the reference specification, no further discussion took place at the working group meeting.

- **ADBAC and BKC**

  The chair presented an overview of the outcome of the e-consultation. All open points have been addressed by the comments received during e-consultation, no further discussion took place at the working group meeting.

- **Active chlorine released from hypochlorous acid**

  The eCA provided the dry weight calculation of the reference specification of hypochlorous acid as requested at the working group meeting I in 2018. The working group members could not agree on the document and requested additional time for verifying the proposal. The chair refused to grant additional time as the active substance is on the agenda of the upcoming Biocidal Products Committee (BPC) meeting. Therefore the member states were advised to raise their concerns, if any, at the BPC meeting.

7. Discussion of Union Authorisation application

Union Authorisation for the product family containing Iodine/PVP-Iodine

All open issues were discussed. The applicant has to submit to the eCA the additional long-term storage stability study immediately after the meeting and the corrosive to metals tests as soon as possible. The eCA is to submit their evaluation and ECHA to launch an e-consultation before the BPC meeting.

8. E-consultations on scientific and technical issues

8.1 Reference specification – TC/TK considerations

The working group members confirmed that the reference specification should be based on the dry weight of the active substance. However, in cases where the solvent(s) cannot be removed from the substance and/or is acting as stabiliser the solvent needs to be considered for the reference specification.

As a consequence of this agreement, the reference specification is set as dry weight but it includes also the solvent(s) without specifying a concentration value. Therefore, solvents may also have to be considered when assessing technical equivalence of an alternative source. It was agreed that the 5-batch analyses shall be conducted with the technical concentrate (TK).

The reference specification of multi-constituent substances should include the whole composition; the main constituents are defined by concentration ranges. Solvents may also need to be considered for multi-constituent substances in the same manner as described above.

8.2 Substance definition of extracts

Solvents shall not be considered for the substance identity of extracts. Therefore, the composition of extracts shall be specified without solvent and if needed based on a dry weight calculation.

If an extract is not stable without solvent, scientific support of that statement must be provided based on experimental data or scientific justifications.

8.3 Copper glass versus dicopper oxide

The working group agreed on two options:
1. The applicant must be demonstrated that 100% of copper oxide is converted to 100% dicopper oxide and that no reactions with the other metal oxides forming the glass matrix take place. This must be supported and demonstrated through analytical data. In this case, the active substance could be considered to be dicopper oxide. The glass matrix would be a "co-formulant" (or

"solvent") which must be considered either for active substance approval or product authorisation.

2. If point 1. cannot be demonstrated or only partially demonstrated by analytical methods and data, the full glass matrix (including dicopper oxide) is the active substance.

8.4 Naming of silver glass

The working group members agreed that the network formers and the element(s) responsible for efficacy need to be considered when defining the substance identities and therefore the number of substances.

A 5-batch analysis for each glass type (i.e. each composition) is required and should be submitted by the applicant.

The reference specifications may include ranges of each metal (oxide) present in the substances. The eCA should propose reference specifications that will be peer-reviewed during the commenting of the draft CAR.

8.5 Radicals generated from hydrogen peroxide

The chair emphasised that the decision whether the generation of hydrogen peroxide radicals should be regarded as a (new) active substance is not in the remit and the responsibility of the APCP working group but requires a policy decision that have to be taken by the Competent Authority meeting or the Biocidal Products Committee. The working groups can only provide technical and scientific support. Hence, the working group could provide technical and scientific advice on the possible need of data and information.

8.6 Practical guide to evaluate the justifications for non-submission of data for the end-point 'corrosive to metals'

A practical guide for evaluating justifications for non-submission of data for the test 'corrosive to metals' was prepared and presented by Germany. The working group members welcomed and agreed on the use of this guide when evaluating waiver justification for the test 'corrosive to metals'. The practical guide will be included in the next update of the Technical Agreements for Biocides (TAB).

8.7 Technical Agreements for Biocides (TAB)

The chair informed the working group members that the next version of the APCP TAB is finalised and will be published in the near future.

9. Any other Business (AoB)

The items raised for discussion under AoB:

- Post approval data for silicon dioxide
- Analytical methods for biocidal products that have been deemed not necessary for the approval of the active substance

will be discussed by e-consultations and if needed at a future working group meeting.

Annex 1 - List of registered Attendees

Country	Members of WG
Denmark	CORDUA Brigitte
Estonia	ILMARINEN Kaja
Finland	KARHI Kimmo
Finland	KORKOLAINEN Tapio
France	SIX Therese
France	WEBER Philippe
Germany	MŰHLE Ulrike
Greece	GATOS Panagiotis
Italy	CATALDI Lucilla
Sweden	MARSH Göran
The Netherlands	HUIZING Tjaart-Jan
Poland	HUSZAL Sylwester
United Kingdom	BOAZ Louise

ECHA staff
KREBS Bernhard (Chair)
GLANS Lotta
MATTHES Jochen
SCHAKIR Yasmin
AIRAKSINEN Sanna

Company	Observer
Diversey BV	VAN CORVEN Danielle
Ishizuka Glass Ltd	SCHURZ Franziska
Ishizuka Glass Ltd	NOGAWA Ai

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
None	---

WG-II-2018
Final minutes
4.7.2018

Minutes of Efficacy WG-II-2018

25 April 2018

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 21st Efficacy WG meeting. There were 5 core and 2 alternate members who participated in the meeting. In addition, 7 flexible members 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. Administrative issues

SECR gave a 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.

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 were declared.

5. Agreement of the draft minutes from WG-I-2018

The Chair informed that there were no comments on the draft minutes of WG-I-2018 and hence they are considered as agreed.

6. Discussion of active substances[1]

6.1 Early WG discussion on free radicals (eCAs: AT, NL, UK)

The early WG discussion took place on NL request. NL, AT and UK have received free radicals active substance dossiers. The eCAs had doubts what kind of tests should be provided to demonstrate efficacy. The intention of this discussion was to clarify what kind of claims are acceptable for the eCAs, i.e. should be mentioned by the applicants in the dossiers, and what kind of efficacy test should be provided.

Claims should be detailed enough to identify the corresponding PT(s). As efficacy tests, basic laboratory suspension tests have been agreed to be sufficient to demonstrate the efficacy.

Regarding dosage recommendation it was pointed out that free radicals have a very short life time and the total ions count (which includes free radicals) can be done via an indirect measurement.

Any factors that can be reasonably expected to influence the efficacy of the generated free radicals, e.g. air humidity, temperature, contact time, soil etc. should be listed in the dossier. Their effects will be assessed at product authorisation (PA) stage. This information might be provided based on literature or experimental data.

Regarding combinations of all/some dossiers into one, the EFF WG was in the opinion that it should be acceptable to use the efficacy data from one applicant for the active substance

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

approval. Then the other applicants included in this dossier should provide efficacy tests at PA stage to demonstrate efficacy of their products.

The second part of the discussion was more PT specific.

It was pointed out that for biocides having later a product authorisation stage, a limited number of test organisms would be acceptable at active substance approval stage. Therefore, it is necessary to clearly describe the claims before the decision related to test organisms will be made. Nevertheless, in case where there is no PA stage and the active substance is used only in treated articles, the spectrum of test organisms should be broader.

With reference to contacttime the EFF WG was in the opinion that it should be a realistic one, and in addition an appropriate control should be done on the untreated material with the same formulation.

7. Discussion of Union authorisation applications

7.1 UA for product family containing Iodine/PVP-Iodine (eCA UK)

There were seven open points for discussion. For one open point concerning virucidal claims an ad hoc follow-up was launched. On the other points the EFF WG agreed with the evaluation made by the eCA.

7.2 Early WG discussion (eCA FI)

During the evaluation of UA application for biocidal products/product families based on hydrogen peroxide the eCA identified issues to be clarified in the context of the coordination role of ECHA. Two agenda points were discussed.

a) Temperature range for hard surface disinfectants belonging to PTs 2, 3 and 4

Considering that disinfectants may be used in a temperature range, the EFF WG discussed the outcome of an e-consultation on temperature requirements for hard surface disinfectants belonging to PTs 2, 3 and 4. Several questions were submitted by the eCA and concluded by the EFF WG.

A question whether it is acceptable that the use temperature range is not defined for hard surface disinfectants was introduced to the EFF WG by the eCA. During the discussion the EFF WG members indicated that a test temperature is already included in the EN standards in order to reflect the proper use of product.

For PT 2 and PT 3 the applicant does not need to define use temperature range for disinfectants used for hard surface disinfection.

For PT4, if products are tested at 20°C and the use temperature is not defined for the respective claim, it has to be indicated as "room temperature". In case a specific claim is made by the applicant regarding use temperature, this temperature should be clearly defined.

On a more general note, the EFF WG agreed that for defining use temperature "ambient temperature" cannot be used.

b) Applicability of the German Engineering Federation (VDMA) guidelines for evaluation of disinfection of packaging before filling (PT 4)

The eCA proposed to discuss whether in addition to the TAB agreement (Disinfection of packaging before filling) more detailed guidelines developed and published by Association of German Machinery and Plant Constructions (VDMA) can be applied to the EFF evaluation of biocidal products intended to be used for disinfection of packaging before filling. Several questions have been asked by the eCA and concluded by the EFF WG.

The EFF WG agreed that the use "Disinfection of packaging before filling" mentioned in TAB could be described using combined description of class III, IV and V machines from VDMA guidelines.

In the opinion of the EFF WG the proposed test is acceptable as the minimum EFF requirement. It was pointed out that a negative control should performed, as already mentioned in the TAB, in order to demonstrate that high temperature alone is insufficient to achieve sufficient control, and there is a need for a biocidal product. Some of the EFF WG members were in the opinion that it is not feasible, and in this particular case it is not necessary to include a negative control. As a compromise it was proposed that negative control should be excluded at least for the tests with bacterial spores, under condition that sufficient justification is provided. In addition a validation similar to EN standards could be requested.

The eCA questioned whether a test report described in VDMA document is sufficient for BPR purposes. The EFF WG indicated that more detailed information must be included in a test report, e.g., dose of disinfectant, relative humidity, contact time, temperature, information on cleaning of the materials prior to the disinfection procedure and surface properties of packaging material.

On a more general note, the EFF WG members were informed that the lastly updated TAB version will be circulated to the MSs for commenting. The EFF WG was invited to comment the entry concerning "Disinfection of packaging before filling" in order to address the above mentioned conclusions.

8. Technical and guidance related issues

8.1 Update on guidance development (ECHA)

ECHA gave an usual update on guidance development. All details are available in the working document: *WGII2018_EFF_8-1_Guidance update*.

8.2 Information on virucidal claims – recommendation for the EFF WG website (AT)

Provision of general information on virucidal claims has been discussed at EFF WGIV2017 and EFF WGV2017. Based on these earlier discussions AT had drafted a proposal for text to be placed at ECHA Efficacy WG webpage as an explanation of the meaning of different virucidal claims. Cefic had sent comments on the proposal shortly before the EFF WG meeting. The EFF WG discussed the text and made proposals for some amendments. The Chair pointed out that even though there are several references to labels in the draft document, the EFF WG can only recommend to potentially include a webpage link to the SPC, whereas the information on the product label is not in the remit of the EFF WG.

The EFF WG agreed that a short introduction should be added to the ECHA webpage prior to the link, bearing in mind that consumers may also go to the webpage directly, not only by following a link from product label.

It was noted that under full virucidal activity it is misleading to indicate that "any currently known virus" is assumed to be controlled – rather e.g. "most known viruses" should be used. It was also noted that the listed viruses should be in the same order under full virucidal activity, limited spectrum virucidal activity and activity against enveloped viruses.

The EFF WG discussed which viruses should actually be listed, only the ones relevant for the use, or also other known viruses belonging to the indicated virus group. During the discussion it was brought up that on one hand consumers want information on all familiar virus names, but on the other hand it may create a false feeling of safety to list virus species not relevant for the claimed use (e.g. ZIKA virus). The EFF WG concluded that the listed viruses are examples, and the list is not meant to be exhaustive. It was agreed that viruses not relevant for the use should not be included in the list.

In the comments sent by Cefic the need to provide information to professionals in the proposed www-pages was questioned, but the EFF WG stated that in previous meetings it was agreed that both non-professional, i.e. general public, and professional users would be the target groups of the www-pages.

It was also discussed whether it is necessary/permitted to describe CEN standards, considering that the standards normally have to be purchased. The EFF WG concluded that the EN standards are also listed and described in the BPR guidance on efficacy, and it should not be forbidden to include description to the www-page.

In addition it was discussed whether the Product Type specific information is needed, since PT is rather a tool for the authorisation, not for the user. AT explained that the PTs are mentioned in the German guidance for pesticides control, but it was agreed that they may be removed.

It was further agreed that AT will clarify where the concept "minimum virucidal activity" used in the EN test descriptions originates from, and that information on that limited spectrum virucidal claim and claim against enveloped viruses is only accepted for hand and skin disinfectants will be added.

Based on the discussion and proposed amendments, AT will send to ECHA a revised proposal by mid-May 2018, and possibly to collect next comments a written consultation will take place.

8.3 Applicability of guidance (ECHA)

The revised version of the document on applicability of the EFF guidance was discussed based on the comments submitted by the EFF WG members.

ECHA informed that TAB applicability in relation to application for biocidal product authorisations will be discussed and agreed in the relevant forum, i.e. Coordination Group.

During the discussion, the EFF WG members supported ECHA proposal to include a link to the newest guidance, available on ECHA webpage, and for the rest to use embedded files.

Several editorial changes were proposed to be included in the document, i.e.:

- numbering for guidance indicated under the same PT,
- clarification regarding the applicability of PT specific parts of guidance,
- clarification for Volume II Efficacy, Assessment + Evaluation (Parts B+C) on changes made for Version 2 compared with Version 1 of guidance in "Comments" column.

The document will be updated taking into account the EFF WGII2018 conclusions and endorsed in a written procedure.

9. AOB

9.1 Request to ECHA for an opinion pursuant to Article 36(2) and 38 of the BPR (eCA IE)

The EFF WG agreed that the efficacy of the biocidal product is sufficiently demonstrated by the submitted data and the conditions of Article 19(1)(b)(i) are met.

9.2 Other information & lessons learned (ECHA)

The EFF WG was informed about upcoming meetings, deadlines and working documents for the meetings, changes in working procedure for active substances approval (it was pointed out that from now on the eCA is in charge of all communications with applicant).

With reference to finalised e-consultations ECHA asked initiating MSs to formulate possible conclusions. It will facilitate the future work of other interested MSs. All finalised e-consultations (including submitted comments) are uploaded on S-CIRCABC.

Additionally, the outcome of the e-consultation initiated on request of IE and regarding suitable laboratory test for lime product was presented. In the e-consultation document the IE CA indicated that due to the low solubility of lime products, some of the laboratory tests may not be suitable to demonstrate the efficacy due to required dilution. Therefore, IE asked the EFF WG members whether there are suitable test standards available for lime products taking into account their extremely low solubility.

The EFF WG members agreed that the EN tests using water as a carrier substance are not suitable for efficacy testing of lime based products. Simulated use tests based on robust and scientifically valid tests are more suitable for efficacy evaluation of lime based products.

A combined table containing timelines for active substance approval and Union authorisation processes was provided to the EFF WG members.

New EFF WG functional mailbox was introduced: BPC-EFFWG@echa.europa.eu. It should be used for all items related to efficacy, i.e. proposals for the meeting agenda, e-consultations, any questions related to any scientific issues, etc.

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
DUH Darja (SI)
GERRITSEN Lonne (NL)
GIATROPOULOS Athanasios (EL)
MARCU Horatiu (RO)
Alternate members
GUNNEWIG Kathrin (DE)
SMITH Ryan (UK)
Flexible members
CAPLIS James (IE)
FONNESBECH VOGEL Birte (DK)
ILMARINEN Kaja (EE)
NIEMINEN Timo (FI)
PECINKOVA Martina (CZ)
RYDMAN Elina (FI)
ZUTZ Christoph (AT)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
STASKO Jolanta
SCHAKIR Yasmin
Applicants
DIVERSEY
HENKEL

Environment WG-II-2018

Final minutes

8 August 2018

Minutes of Environment WG-II-2018

19 - 20 April 2018

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 17 participants present, of which seven were core members (one represented by alternate) and ten flexible members. One representative from accredited stakeholder organisation were present. Applicants were registered for their specific substance discussions.

The Chair informed the WG members that Anne Munch Christensen and Peter Okkerman will no longer participate in WG meetings, partly due to other assignments, and thanked them for their long-time valuable contributions at TM as well as WG meeting level.

Participants were further 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 the WG members to provide any additional items. The agenda was agreed.

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 was declared.

5. Agreement of the draft minutes from WG-I-2018

Due to missing comments in the minutes of two cases, the minutes will be agreed by written procedure - to be initiated after the meeting.

Action: SECR

6. Discussion of Union authorisations

6.1 BPF based on Iodine (eCA UK) – PT 3

One point related to classification was closed trilaterally before the meeting. One point related to the exposure assessment was presented for information. The PAR can proceed to the BPC.

Actions:

- **SECR** to prepare further clarification on the update of the classification procedure for the AS (harmonised process versus update as result of product authorisation).

6.2 Early WG: Early WG related to a Hydrogen Peroxide Product Family - disinfection of drip irrigation systems (PT 2)

One point relating to exposure was discussed and closed before the meeting. Three further items related to exposure were discussed during the meeting and all points were closed. The following action was agreed on in the WG.

Actions:

- DE question on the point closed before the meeting will be followed up bilaterally after the meeting with NL, ENV WG will be informed on the outcome.
- **SECR** to prepare a **TAB entry** on the agreed default value and the proposed emission scenario.

7. Technical and guidance related issues

7.1 Update on guidance development, issues identified for the AHEE (ECHA)

SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. Updates from WG members during the meeting have been included after the WG meeting (see updated table in **Appendix 1** below).

7.2 Direct emission to surface water in urban areas (FI, ECHA)

FI/SECR presented a document to clarify how the scenarios to assess direct emission to surface water in urban areas, i.e. the bypass STP (mixed sewer) and direct rainwater discharge (separate scenario) should be used in the risk assessment and how they should be used for decision making.

On the application of the bypass STP (mixed sewer) and direct rainwater discharge (separate sewer) scenarios, the WG agreed that for active substances and biocidal products the separate sewer system scenario should be calculated for PT 6, 7, 9 and 10 (in connection with the city scenario). This should be used for the decision making process and should be considered as a Tier I. The bypass scenario does not need to be calculated.

On the direct emission pathway to surface water in urban areas, the WG agreed that the bypass scenario should not be considered. The scenario for direct rainwater discharge should nevertheless be used for service life and application.

Actions:

- DT point 1: Tier 2 to be defined. **NL** to follow up.
- **SECR** to prepare a **TAB entry**

7.3 Follow up on open items from WG-I-2018 (ECHA)

7.3a PT 18: Pesti'Home French survey on domestic uses of pesticides by non-professionals (FR)

FR presented Pesti'Home data including an introduction to the study framework and expected data from the survey pointing out the potential relevance for refinements in PT 18. A point was made that the data could possibly define input parameters in PT18 (examples) or product authorisation.

7.3b PT 18: Final draft emission scenario for insecticides in mink farms (DK)

DK presented a final draft document following a previous e-consultation on an emission scenario for PT18. In general the WG agreed to the scenario, however, it was proposed that only application to arable land is considered relevant and not application to grassland. The updated scenario will be presented at SETAC conference in May. The actions are summarised below.

Actions:

- **DK** will update the scenario by deleting any parts referring to grassland application and provide the updated scenario to **SECR**.
- **DK** to add a sentence explaining that the PEC calculation for soil should be done in line with the OECD ESD no. 14 for PT 18.

- **SECR** to include the final version in the **TAB.**

7.3c PT 6-10: Proposal to calculate PECsediment for direct emission to water (NL)

NL presented a proposal on how to calculate PECsediment for direct emission to water (PT6-10). The WG could not agree on the document and requested further worked calculation examples. NL agreed to provide them. The item will be followed up by the AHEE in a written procedure.

7.3d PT 6: Proposal for a scenario for in-can preservation of fuels in storage tanks (NL)

The WG agreed to the scenario presented by NL and to the revised default values as presented by NL. With regard to the purification step, the WG agreed to the proposal 1.b (using SimpleTreat 4.0 with the proposed alterations). The definition of the RMM was discussed and the proposal was adjusted but the agreement is not within the remit of the WG. Furthermore, CEFIC noted SimpleTreat as an industrial scenario was undertaken within an Ecetox project resulting in a publication. SECR would check with an Ecetox representative to confirm this. The following actions were agreed on.

Actions:

- **NL** to crosscheck default values for SLR to be used in SimpleTreat 4.0 for the industrial wastewater treatment (focus on fuel storage facilities).
- **SECR** to include the scenario in the **TAB** once finalised.

7.3e PT 18: Generic treatment areas assigned to specific pest (UK)

Following an update of the proposal by the UK from a WebEX meeting of WG-I-2018, the WG agreed to the proposed areas. The following action points will be covered via a written procedure (UK to prepare proposals/revised document version).

Actions:

- Default values to be deleted, only explanation of non-relevance should remain.
- Area to be assigned for relevant sections and **UK** will prepare a proposal.
- **SECR** to include the document in the **TAB** once finalised.

7.3f PT 8: Temporary anti-sapstain wood preservatives (DE)

Four points were presented on the assessment of temporary anti-sapstain wood preservatives and three were closed. One point could not be closed as the item is not within the remit of the WG and no conclusion was drawn. Several concerns were collected relating to this point. UK pointed out that the issue may be related to Article 58 concerning the downstream labelling of treated articles and outside the remit of the WG. DE is aware the issue is Article 58 issue but also a RMM. Furthermore, it was pointed out that there are similar situations affecting other product types. NL pointed out the issue should be forwarded to the BPC and relates to Article 58. SECR noted they will look into opinions from the BPC for a similar case which was discussed. The following actions were agreed on.

Actions:

- **DE** to adjust the document taking into account the WG meeting conclusions (e.g. deleting option A) and to provide the final document to **SECR**.
- **SECR** to include the document in the **TAB.**

7.3g Definition and PEC calculations for service life of preservatives (NL)

One point was discussed but several concerns were made and it was agreed that sending comments to NL would be the best approach. Therefore, no conclusion was drawn and the document will be followed up via a short commenting phase as the proposal affects EUSES quick fix implementation.

7.4 PT 2: Draft scenario for ponds (FI)

FI informed the WG that the applicant has withdrawn the application for which the new emission scenarios for disinfection of garden ponds/natural swimming pool were relevant. Therefore, the WG agreed not to discuss the scenarios for the time being, since related emission scenarios are in place to cover the uses.

SECR will follow up on the scenarios if they would be needed in the future.

7.5 Simplification of exposure assessment (ECHA)

SECR initiated a discussion on how to simplify the exposure assessment at WG-V-2016. The discussion was followed by an e-consultation, in which WG members were invited to provide proposals for further simplification. A summary of the outcome was presented at WG-III-2017 were it was agreed that SECR will extend the document including the additional discussions that took place at WG-III-2017 and draw conclusions on concrete proposals. These conclusions were presented for confirmation by the WG:

A. Harmonised exposure assessment tools

Emission estimation: Harmonised ESD excel sheets will be prepared by the leading Member State or ECHA (to be agreed case by case) whenever a new ESD is finalised, an existing ESD is revised or amended or a new scenario is developed.

If the updated EUSES software is in place, the ESD excel sheets will be used as basis for an update of the next software versions.

Fate and distribution: Since ECHA decided to take over the development of EUSES, further consideration on the fate and distribution models will be taken up in the frame of the EUSES update project(s).

B. RMM

At active substance approval stage, the exposure and risk always has to be assessed. The standard RMM can be used only at product authorisation stage to replace a risk assessments.

An overview of standard RMM for uses for which the risk assessment could be skipped should be prepared (work to be discussed/streamlined with BPC).

C. Acceptance of local risk

DE and FR to prepare a proposal for clarification on bait box scenarios in gardens in PT 18 (e.g. for ants) to further clarify which parts of the garden are covered by "use around the building".

DE will discuss a potential follow up with FR and get back to SECR with a proposal.

SECR to prepare and submit a discussion document for BPC to clarify possible differences in the assessment of restricted small scale applications (e.g. bait boxes) in gardens.

Accepting local risk by claiming that recolonization is possible was considered to add an unnecessary additional step in risk assessment. It was proposed instead to consider excluding the treated area from risk assessment.

D. Risk envelop approach

SECR to launch an analysis of ESDs to identify the worst case scenarios after WG-II-2018 (participants: FR, NL, DE, CH, DK, coordination by SECR). Work distribution and timelines to be agreed at WG-II-2018 (see also point G below).

Proposed work distribution, to be clarified in a matrix after the meeting (**Action SECR**):
FR: PT 8, 18, disinfectants
NL: PT 6-10, 11, 12, 13, 21
DE: PT 6, 14, 18, 19, disinfectants
CH: PT 8, 18, 19, 14
DK: PT 8, 18
CEFIC: TBD

Timing: September – November WG meeting, to be decided after the work distribution is agreed.

E. Substance properties

MS did not agree that a lighter exposure assessment would be performed for any active substances to be included for Union List.

F. Use of already existing scenarios for new uses

eCAs should carefully consider if a new use could be covered by an existing scenario in order to limit the development of new scenarios in particular for niche uses.

The need for new harmonized exposure scenarios should always be decided at an early stage of the evaluation process through an e-consultation or early WG discussion.

G. Cover more scenarios at AS approval stage

Views expressed at WG-II-2018 (no conclusion drawn since partly not in the remit of the WG):

MSs agreed that more uses should be assessed at AS approval in particular when it can be foreseen that the (existing) AS has been authorised for uses with more significant emissions than the intended safe use under AS approval. However, it needs to be checked if this approach is lawful.
MSs to provide an overview of intended uses of substances per PT on the basis of national authorisations.
If such an overview was found currently incomplete due lack of statistics among MSs, the proposed approach will be delayed to AS renewal.

One major issue is how to ensure that the data set agreed at WG matches all intended use patterns when only a fraction of the actual uses will be specified (see section 4 below).

Link to point D above (i.e. add to work distribution): perform calculations with a dummy substance and build a pyramid of worst case uses and their coverage per environmental compartment. Where uses assessed at AS approval do not cover the authorisations of uses given by the pyramid, the respective worst case use(s) should be added to the CAR (sharing the workload between CA, AS approval applicant(s) and authorisation holders needs to be clarified). The maximum allowed dosage should be established for each assessed use if possible.

Assessment of uses at the renewal stage of active substance to be followed up (additional uses known from product authorisation to be assessed?).

H. Simplification of metabolites exposure assessment

WG agreed that at AS approval if at first tier major metabolites are found much less toxic (by a factor of 10) and no more persistent than AS, there is no need for their full quantitative risk assessment (with the exception of groundwater assessment).

Additional item: Formal/procedural aspects regarding CAR/PAR

Several formal items concerning the CAR/PAR preparations have been already agreed at WG-III-2017, some additional clarifications were included and agreed by the WG:

- Do not repeat complete ESDs in Part B, but make references to the ESDs and TAB agreements applied and only publish the variables and possible deviations. It should be reproducible.
- Do not include full model output files from PEARL as this leads to extensive documents. It is rather important to present all relevant input parameters for calculating exposure concentrations, settings and results in a table. However, include EUSES export files or ESD excel sheets as well as pdf files as Appendix.
- Do not deviate from defaults without any scientific/technical substantiation even when risks has been identified unless sufficient information is available demonstrating that the applied methods are unrealistic for the current active substance and products.
- If it is necessary to deviate from default parameters and/or a new scenario must be applied, it is advisable to discuss this with the WG prior to the commenting phase.
- For complex substances and/or substances with multiple PT's, it may be beneficial to discuss Part A first and start with the risk assessment once agreement on endpoints is reached (this was done in the past for e.g. glutaraldehyde).
- The CAR is the backbone for future product authorisations. The document should be as complete as possible and all crucial data gaps should be filled before product authorisation starts. Approval of an active substance based on a use with negligible emission to the environment, while uses with emissions (e.g. outdoor uses) could be expected may delay product authorisation. The same holds for substance approval based on one or two safe PEARL scenarios while union authorisation are expected (please refer also to item G above).
- WG members addressed in addition the need of revising the CAR/PAR template (simplification, reducing redundancies, e.g. do not repeat tables in the CAR/PAR, PEC values / PNEC values should be filled in only once).

Action:

- SECR to forward the points to the other WGs and initiate internal discussion initiated on how to implement those items in the working procedures (or other relevant documents).

7.6 Follow up on ENV RAAF (Read across assessment framework) – outcome e-consultation (ECHA)

The SECR reported the outcome of the e-consultation that was conducted in March 2018. In summary there was general agreement on the implementation of the RAAF concept to the biocides environmental assessment. In addition it was agreed that a harmonised documentation of read-across cases and assessment should be determined. Some items where identified for further development, e.g. modification of the reporting template (simplification).

Actions:

- **SECR** to prepare an updated version of the read-across template and to provide further instructions for reporting read-across cases in CAR and/or IUCLID dossier.

8. AOB

8.1 Other information & lessons learned

The following "Lessons learned" were shared:

General items: Implications of proposed changes in existing scenarios in context of an a.s. discussion should be analysed first (by MS proposing change) to assure change is feasible. Full scenario with agreed changes as well as new scenarios agreed at WG meeting to be provided after the WG by the MS proposing change/new scenario - for inclusion in TAB. SECR to assure meaningful and complete TAB entries (not only agreed additions to scenarios but full scenarios).
WebEx meetings to follow up open items of WG meeting to be set up with sufficient time after WG meeting

The following "**Other information**" was provided:

Change of the AHEE mandate: Revised mandates for the AHEE agreed at BPC-24, published on the ECHA webpage: https://echa.europa.eu/documents/10162/20733977/mandate_bpc_ad_hoc_wg_ee_en.pdf/08a04342-18ab-4db8-8d4d-0e7002ae9215
Implications: New emission scenarios, changes in existing scenarios and default values discussed and agreed from now on by AHEE. Discussions always to be initiated via an e-consultation. ENV WG involved only if no agreement by the AHEE (more physical AHEE meetings in the future).
What remains in the remit of the ENV WG: Discussion/agreement of revised or new full ESDs, clarifications on how to interpret existing guidance.

Change of working procedures for AS approval:
Main changes agreed at BPC 24:

- Criteria for accordance check amended for consultation of PBT and ED EG in light of experience: obligatory consultation by eCA removed
- eCA in charge of all communications with applicant due to confidentiality issues (WP for UA will also be updated accordingly)
- Reference specification and reference source are specifically mentioned as mandatory requirements for submission of CAR

Early WGs: Provide early WG meeting proposals (AS/UA) as early as possible, at the latest six weeks before WG meeting
Flexible format: Word document or discussion table, plan-in an e-consultation of the ENV WG or AHEE

- Effect related items => e-consultation of ENV WG
- Emission scenario/default value related items => e-consultation of AHEE

Responsibility of eCA to prepare all documents for e-consultation and WG meeting. Before starting early WG on new emission scenarios, ask yourself if a new scenario is really needed - coverage by existing scenario possible?

Proposal for e-consultation procedure:
AS/UA-specific e-consultation (e.g. effect related)

- eCA provides documents and proposed commenting timeline to SECR (default: 10 working days)
- SECR launches consultation of ENV WG via a dedicated newsgroup

- eCA evaluates the outcome and reflects outcome in CAR/PAR
- No further follow up at WG meeting level (in line with TOX WG)

General e-consultation on emission scenarios/default values

- *Ask yourself if a new scenario is really needed* - coverage by existing scenario possible?
- MS provides documents and proposed commenting timeline to SECR (default: 10 working days)
- SECR launches consultation of AHEE via the common newsgroup
- MS evaluates the outcome and prepares summary and conclusions
- If conclusions clear: SECR informs AHEE/ENV WG
- If conclusions not clear: MS prepares open points in DT format for AHEE
- Final outcome following AHEE discussion presented at next WG meeting

Endocrine disruptors: ED criteria provided in

- Commission Delegated Regulation (EU) 2017/2100
- Applicable for biocides from 7 June 2018
- Guidance being finalised by ECHA/EFSA/JRC

Implementation documents agreed at the CA meeting:

- Implementation for active substances: CA-March18.Doc.7.3.a- Final[1]
- Implementation for biocidal products: CA-March18-Doc.7.3.b-final[2]
- For each biocidal active substance:
- It is 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)
- Exception: if the eCA proposes clear non-approval, a conclusive ED.

Biocide CAs are encouraged to inform as early as possible ED EG Secretariat on their plans via their ED EG member (if nominated), copying in the Biocides Secretariat:

- ED EG Secretariat: ed_eg@echa.europa.eu
- Biocides Secretariat: biocides-bpc-active-substance@echa.europa.eu

ECHA will periodically contact ED EG members regarding their plans to bring cases to the meetings, ED EG Secretariat drafts annual work plan (substances, general items) that is distributed to the ED EG.

General items: MS should check your S-CIRCABC settings: Do you receive notifications if documents are uploaded?

- SECR will not send separate emails if discussion tables, conclusions or minutes/final minutes (incl. AHFs) are uploaded
- We continue to send separate emails for e-consultations or other items for which no pre-defined timelines exist

IMO Convention for Cybutryne: ECHA together with EMSA is providing scientific support to the COM in the proposal to include cybutryne in the Annex 1 to the International Convention on the Control of Harmful Anti-Fouling Systems on Ships. The initial proposal successfully passed through PPR 5 but IPPIC argued that although the assessment done for BPR did not reflect exposure scenarios on a global scale. ECHA/EMSA/COM are now working on a comprehensive proposal to be submitted during 2018

E-consultation on QSAR guidance/E-consultation on FOCUS training: Reminder was provided at the WG meeting to respond.

WG confirmed need for training on the estimation of degradation kinetics from environmental biodegradation studies on biocides.

- Aim: ensure that everyone has the same basic understanding of the requirements for a kinetic assessment under the BPR.
- UK indicated availability to contribute actively.

- Workshop(s) as possible next steps.

8.2 Tasks and activities of ECHA's Endocrine Disruptor Expert Group

An overview on the tasks and activities of the ED expert group was provided.

8.3 Update on EUSES related activities

SECR provided information on the two ongoing EUSES projects:

<u>EUSES ongoing update (quick fix)</u>

- Focus is on biocides only, IT technology and User interface remain unchanged. Release of EUSES 2.2.0 foreseen Q4 2018/Q1 2019

<u>Considerations for the future (major EUSES update)</u>

- Workshop in Brussels in June 2018 to identify needs for REACH and biocides

Appendices:

Appendix 1:

Agenda item 7.1: Update on guidance development, issues to be sent to the AHEE

Note:

- Issues unchanged since WG-V-2017 are highlighted in grey shading.
- Closed issues are ~~stroke through~~.

1. Guidance related documents

No.	Title (current leader)	Status
1.2	2nd EU Leaching Workshop for PT 8 (**ECHA**)	*Reminder:* ***Members*:** Start to perform a risk assessment for the new TIME2 (= 365 d), however not using it for decision making. Send the risk assessment to SECR via CIRCABC. ***SECR*** opened a Newsgroup on CIRCABC[1] in order to collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year). **SECR** to include additional time also in the Excel sheet for PT 8 currently under preparation.
1.3	Fish net scenario (**ECHA**): discussion on the usefulness of the new version of MAMPEC to be initiated	Discussion was started by NO. **Possible inclusion in MAMPEC discussed with Deltares at AHEE-1, funding to be clarified by SECR (=> potentially in 2018)**.
1.4	Guidance on aggregated exposure assessment (**DE**)	The discussion of the draft guidance is re-scheduled for an electronic procedure, to be started in Q1 2017. Documents were provided by DE to ECHA, SECR initiated e-consultation after the WG meeting. **Discussion in Q3 2018? Legal situation to be clarified.**
1.5	TAB (**ECHA**): Technical Agreements on Biocides	The agreed items from WG-IV-2017 to WG-I-2018 will be included in the next TAB version (still to be decided if v1.4 or v.1.5, depends on the finalisation date of the APCP part). **The next TAB version is scheduled to be distributed for commenting mid-April 2018.** **Alternative solution to publish agreed WG meeting documents immediately after agreement under discussion.**

[1] **Path:** /CircaBC/echa/BPC-WG/Newsgroups/ENV WG Impact assessment for PT 8 - new TIME scheme
Browse url: https://webgate.ec.europa.eu/echa-scircabc/w/browse/97974dd4-2b7c-411b-99c1-9f8de5090990

No.	Title (current leader)	Status
~~1.6~~	~~ESD for PT 6 (**DE**)~~	~~DE has revised the ESD following comments received. The ESD was endorsed at WG-I-2017.~~ **~~The ESD was uploaded on the ECHA webpage~~**
1.7	Evaluation of ESD PT 14 (**DE**)	Shortcomings of the current emission scenario document for rodenticides (ESD PT14) became obvious within the national product authorisation of rodenticides. UBA Germany has initiated a research project to review the described scenarios and assumptions. The project is scheduled from January 2016 to November 2017. A commenting round was started on 11th September 2017 with ad deadline for providing comments of 13th October 2017. **First discussion was held at WG-I-2018, final draft was distributed for review on 17.04.2018.**

2. Items identified for the AHEE (related to exposure assessment)

No.	Title (current leader)	Status
ASSIGEND ITEMS		
2.1	PT 3: Scenario for disinfection in aquaculture ⇨ *Disinfection project/EMA visit*	ECHA contracted out the preparation of a first proposal. First discussion took place at WG-I-2017, comments received during the commenting period to be added. **Revised version will be provided for discussion/agreement at WG-IV-2018.**
2.2	Clarification on DT50 values according to the FOCUS guidance to be used for modelling purpose and as trigger value (for higher tier studies/PBT assessment) ⇨ *WG-I-2016 – item 6.3b*	**DE/UK** volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined.
2.3	PT 11: Which fraction should be used to calculate the PEC in soil following deposition from air? ⇨ *WG-IV-2016 – item 6.3*	**NL** volunteered to take over the item. Timing to be defined.
2.4	PT 4: Is splitting up the release from on-site/off-site STP in the case of large breweries relevant and is the proposed percentage (on-site = 33% / off-site = 67%) realistic? ⇨ *WG-V-2016 – item 6.1*	**NL** volunteered to take over the item. Timing to be defined.

No.	Title (current leader)	Status
2.5	PT 8: Proposal for emission scenarios on how to assess short term antisapstain treatments *WG-III-2016 – item 6.7/BPC-17*	DE took over the item, a thought starter was presented at WG-I-2018 followed by an e-consultation and discussion at WG-II-2018. Final document to be provided by DE for publication by SECR.
2.6	PT 6: Development of an emission scenario for the preservation of unrefined fuels ⇒ *WG-V-2015 – item 7.3*	Item taken over by NL (early WG meeting discussion in the frame of an UA case). First discussion at WG-I-2018 followed by an e-consultation and a second discussion at WG-II-2018. Final document to be provided by NL for publication by SECR.
OPEN ITEMS (priority indicated in colours: high = red, yellow = medium, green = low; prioritisation based on the time lines provided in Annex III of the RPR)		
2.7	PT 18: How to derive values for the cleaning efficiency FCE (=> Release and exposure estimation of the biocidal product during cleaning step) ⇒ *WG-III-2015 – item 6.4*	AHEE member to take over item to be assigned.
~~2.8~~	~~PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application rate per surface (leaching rate assuming 100% leaching) or use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8).~~ ~~⇒ *WG-IV-2015 – item 6.3*~~	~~*Item was solved in the frame of item 8.3 of the WG-IV-2017, therefore no longer relevant (a factor of 40 was agreed).*~~
2.9	Development of RTU/small scale application scenario for PT 18 (household and professional use) ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.10	Development of a proposal on how to use Fsim in an aggregated exposure assessment for PT 18 ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.11	Refinement options for PT 11 once through and large recirculating systems ⇒ *WG-II-2016 – item 6.8/6.9*	AHEE member to take over item to be assigned – document form industry awaited.
2.12	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the	SECR to initiate.

No.	Title (current leader)	Status
	emission pattern for soil exposure (batch-wise vs. continuous release). ⇨ *WG-III-2016 – item 6.4 (AHF)*	
2.13	PT 7: Revision of the ESD (inclusion of the formulation step, alignment of equations with A/B tables) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.14	PT 9: Definition/revision of fixation factors for PT 9 – leather applications ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.15	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned. *Note: SECR to check original entry, may be covered already by item 7.3g prepared by NL.*
2.16	PT 9: Concentration in soil in PT 9 rubber-roof membrane scenario ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.17	Focus SWASH: Use of the model for calculation of PEC in sediment (PT 3, run-off from soil) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.18	PT 19: review of default value for Fsim (worst case to apply the Fsim of PT 18 to PT 19?) ⇨ *BPC-19 – AP 07.05*	AHEE member to take over item to be assigned.
2.19	Development of guidance for bees and non-target arthropods ⇨ *CG (2017)*	AHEE member to take over item to be assigned. *Note: DE and CH have initiated national projects to collect information which could be the basis for a future guidance document.*

Human Health WG-II-2018

Final minutes

4 July 2018

Minutes of Human Health WG-II-2018

23 – 24 April 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 34 members registered, of which 9 were core members. One stakeholder observer 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. Agreement of the draft minutes from WG-I-2018

The minutes were agreed without further changes.

6. Discussion of active substances

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

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

7. Discussions on Union authorisations

7.1 UA for product family containing Iodine/PVP-Iodine (eCA UK)

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

8. Technical and guidance related issues

8.1 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 included. The document is available in S-CIRCABC to members and associated stakeholder organisations.

8.2 Assessment of liver effects

UK introduced the document, informing that all aspects of the JMPR document[1] (2015) were taken over in their proposal. The 15% value also comes from this document in the section related to normal biological variation.

One member clarified that the JMPR considers any isolated liver weight increase as non-adverse, as long as no other effects are seen (no set value). The member supported this deviation from JMPR as it is provides a clearer way to assess the adversity of liver hypertrophy.

Overall, the revised UK proposal was supported by the members. While some members supported the revised UK proposal as such, others preferred to remove all aspects which are not needed as not directly related to the question (e.g. how to deal with historical control data/outliers, statistics, how to integrate individual studies in the whole data set/risk assessment, thyroid effects). SECR informed that EFSA also provided preliminary comments on the UK revised proposal and had similar suggestions.

UK agreed to remove the references to historical control data, outliers, sub-chronic to chronic extrapolation and thyroid effects. UK asked whether the members wanted to follow the JMPR document, noting that any isolated liver weight increase would be considered as non-adverse. The members agreed with the 15% value proposed by UK; some of them noting that in principle a higher value could be acceptable but there is too limited data to support this.

CEFIC welcomed the revised proposal and the 15% value, also noting that higher liver weight increases could be adaptive. CEFIC suggested to clearly indicate that a case-by-case assessment, with expert judgement, is needed. It was however noted that this element is already included in the proposal. CEFIC further noted that while enzyme induction is sometimes relevant for liver hypertrophy, it is not always conclusive. CEFIC suggested to reword that part.

UK will provide a revised version of the document. SECR suggested following the TAB format, i.e. a short text to be agreed with the members, with a supportive document in Annex. A commenting round will follow.

8.3 Local risk assessment – proposals for new TAB entries

SECR presented the revised proposals where all comments were included and responses were provided. The WG agreed on the proposals with minor additional changes.

8.4 Toxicological relevance of metabolites in groundwater

SECR informed the members of the status of the work. No discussion took place.

8.5 Dietary risk assessment for PT 19 skin application

The main point of the discussion was the relevance of the consumer exposure via food to PT 19 products applied on skin.

Some WG members considered the transfer of an active substance from hand to food and then to mouth very incidental, thus not supporting the need to perform a dietary risk assessment. Instead, risk mitigation measures (RMMs) and labelling instruction would be sufficient to prevent from such food contamination. Other WG members informed of national cases of contamination of handpicked food by repellents.

The majority of the WG members agreed that the exposure to repellent residues via food is not negligible, but measurable. The majority of the members supported the elaboration of a scenario for the estimation of dietary risk assessment of repellent residues. The scenario presented by FR was however considered too conservative and the members

[1] WHO, 2015: Pesticide residues in food: WHO Core Assessment Group on Pesticide Residues. Guidance document for WHO monographers and reviewers WHO/HSE/GOS/2015.1, 1-106 pp. http://www.who.int/foodsafety/publications/jmpr_guidance_document_1.pdf

therefore recommended ARTFood to explore whether appropriate methodology could be developed. It was proposed to harmonise the risk mitigation measures to be applied when unacceptable risk is identified.

9. Any other business

9.1 Other information & lessons learned

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

CAR/CLH template

A common template to be used for biocidal active substances (CAR) and CLH proposals is now available at the ECHA website[2].

EFSA Guidance on dermal absorption

The BPC endorsed on 6 March 2018 the document that establishes the EFSA Guidance on dermal absorption (2017) to be used for biocides: "*The applicability date of the EFSA Guidance on dermal absorption (2017) should be determined according to the rules set for the applicability of guidance for biocidal products and biocidal active substances. As the basis for establishing the specific applicability timelines, the date of endorsement of this document at the BPC should be used.*"

Further clarifications will be necessary to clarify the approach to biocides, where the EFSA guidance would not be directly applicable. SECR asked the members to provide input by e-mail to SECR regarding any such issues.

Change of working procedures for AS approval

An amended working procedure for active substance approval was agreed at BPC-24. For WG members, the most relevant changes are:

- Amended criteria for accordance check with regard to consultation of PBT EG and ED EG: obligatory consultation by eCA removed
- The eCA is now in charge of all communications with applicant
- Reference specification and reference source are specifically mentioned as mandatory requirements for submission of CAR

Next WG meetings

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

- 29-30 May: virtual meeting
- 3-5 July: most likely virtual meeting
- 10-21 September: most likely physical meeting

9.2 Tasks and activities of Endocrine Disruptor Expert Group (ED EG)

The ED EG Secretariat provided a presentation on the tasks, activities and organisation of the ED EG. The presentation is available in S-CIRCABC to MSCAs and to associated stakeholder organisations.

[2] https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/

Annex 1

Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
ARAPAKI Niki (EL)
MAXIMILIEN Elisabeth (FR)
LORI Julia (FR)
HOLTHENRICH Dagmar (DE)
SCHUMACHER David (DE)
BOS Carina (NL)
BRESCIA Susy (UK)
ROBINSON Julie (UK)
Rapporteurs
THOMAS Sally (UK)
Flexible members
HAUZENBERGER Ingrid (AT)
HÖLZL Christine (AT)
KINZL Maximilian (AT)
BRYS Kristel (BE)
TORDOIR Charlotte (BE)
ROSSIER Nadine (CH)
BÜHLER Dominique Anne (CH)
STRAUCH Stefanie (CH)
SUMBEROVA Hana (CZ)
GOTTLOB Kathrin (DE)
PETERSEN Annika Boye (DK)
SCHMIDT Marianne (DK)
HYVÄRINEN Tuija (FI)
RYDMAN Elina (FI)
PUPIER Cindy (FR)
REY Marion (FR)
GAUSTAD Astrid (NO)
HAUGSTAD Kjetil (NO)
LEEVES Sara (NO)
LÅSTBOM Lena (SE)

ECHA Staff
AIRAKSINEN Antero (Chair)
ANTAL Diana
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
MYÖHÄNEN Kirsi
PAPADAKI Lina
RUGGERI Laura
JUTILA Arimatti
SCHAKIR Yasmin
Applicants
Diversey
SCC-GMBH
ARCHE Consulting
JCS International
EDF
Buckman Laboratories NV
API-Additives for Paper Industry GmbH
Foxyde
Stakeholders
COREA Namali (CEFIC – expert)
Advisors
BOAZ Louise (UK)
GORECKI Roman (PL)