Final minutes of the Working Group meeting I in 2021 Analytical Methods and Physico-Chemical Properties (Meeting date: 15-16 March 2021 – WebEx meeting)

01 June 2021

1. Welcome and apologies

The meeting was a WebEx-meeting. The Chair welcomed the participants of the working group meeting. CEFIC was present at the meeting as an accredited stakeholder organisation (ASO) with one representative. The following applicants were invited to the meeting as an observer for their active substances or Union authorisations:

- Evonik Nutrition & Care GmbH
- Ercros S.A.
- Christiansen SARL
- ARCHE Consortia

Participants of the working group were informed that the meeting is recorded, but solely for drafting the minutes and that the recording will be destroyed after the agreement of the minutes. The recording will not be released to anybody outside ECHA and any further recording is not allowed.

2. Administrative issues

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

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:

- Age of 5-batch analyses
- Carrier-based biocidal products
- Interpretation of 'ambient temperature' during long-term storage stability test

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 agenda. None was declared by the working group members.

5. Agreement of the draft minutes from WG IV 2020

The working group members did not provide comments on the draft minutes of WG IV 2020. No comments were expressed at the meeting. The minutes of the working group meeting IV in 2020 were agreed by the working group members.

6. Training on physical hazards

Training on physical hazards was given to the working group members by the German Federal Institute for Materials Research and Testing (BAM).

7. Outcome of e-consultation and discussion

E-consultations and early working group discussions – clarifying the concepts

ECHA gave a presentation clarifying the concepts of e-consultations and early working group discussions, as the understanding of these terms was different between the four working groups. The presentation is available to the Working Group members on S-CIRCABC.

E-consultations and discussion

Several working group members were seeking advice from others by initiating e-consultations. The received replies were presented and, in some cases, discussed. Hence, the working group provided advice to the requesting member states.

8. Discussion of Active substances

8.1 L-(+)-lactic acid PT06

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

9. Discussion of Union authorisations

9.1 Union authorisation for product(s) containing Permethrin

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

9.2 Union authorisation for product(s) containing active chlorine released from chlorine

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

9.3 Union authorisation for product(s) containing active chlorine released from sodium hypochlorite

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

10. Technical and Guidance related items

10.1 Working Group recommendation on in situ generated active substances

ECHA gave an update on the progress of the revision of the Working group recommendations on in situ generated active substances. A new meeting with the corresponding task group is planned for mid-April 2021.

11. Any other business

11.1 Presentation on alternative ways of working

ECHA gave a presentation on ideas for alternative ways of working, which would aim to facilitate the process and pace of work of active substance and Union authorisation applications. The alternative ways of working are based on the discussions at the member states workshop which took place in 2019. The alternative ways of working were presented for information and will be further discussed at the BPC meeting. The working group members exchanged their views on the proposals.

11.2 Age of 5-batch analyses

The Guidance on the BPR: Volume I Parts A+B+C, Version, 2.0, May 2018, page 37, Section 2.5.11.1 General requirements, bullet point number 12, states follows:

"In general, batches tested should be no older than five years from the date of dossier submission. Deviation is possible if the applicant can ensure the manufacturing process has not changed. Quality control data should be provided if the age of the batch analysis is >5 years but <10 years. The batch analysis should not be older than 10 years."

The working group members discussed the correct interpretation of "from the date of dossier submission. It could be interpreted as

- the date the applicant submits the dossier to the eCA
- the date the eCA submits the draft evaluation to ECHA accordance check

It was mentioned that applicants cannot be made responsible for cases where the evaluation by the eCA is exceeding 10 years with the consequence that an up-to-date 5-batch analysis should be requested. Therefore, the submission date of the dossier to ECHA for the accordance check should not be regarded as relevant. However, it was also highlighted that there are cases where the evaluation has been ongoing for more than 10 years and it cannot be confirmed that the original 5-batch analysis remains representative. It was mentioned that a new 5-batch analysis is required for renewal of active substances. The chair highlighted that the age of the 5-batch analysis was introduced due to the frequent commenting during the peer-review of the draft CAR's. In particular, member states already requested new 5-batch analysis from applicants and sources were removed as reference source due to the age of the 5-batch analysis. Consequently, the same approach must be followed for all other cases, otherwise equal treatment of applicants cannot be granted. One option which was suggested was that QC data could be used to confirm that 5-batch analyses also older than 10 years are still representative. Since such QC data are expected to be routinely performed by industry and this would not require a new study. QC data could be submitted and added to the CAR on a regular basis. It was concluded that ECHA will continue to apply the current practice of using the date of the submission of the draft CAR to the accordance check until a different agreement is made.

11.3 Carrier-based biocidal products

A general exchange of views about the applicability of the document 'CA-Nov16-Doc.4.3' with regard to physical hazards was initiated.

The working group members explained that they evaluated several carried-based products and requested data on the liquid to address classification and labelling, including tests on corrosion to metal. The working group members expressed their doubts on the applicability of the CA-document and the need for its revision. The chair stated that ECHA will discuss internally the revision of the document and the process to be followed.

11.4 Temperature during long-term storage stability test

Annex III to the BPR requires a long-term storage test at ambient temperature. Neither the BPR nor the BPR guidance clearly define the term 'ambient'. The CROP LIFE TECHNICAL MONOGRAPH N°17, 3RD EDITION; GUIDELINES FOR SPECIFYING AND MANAGING SHELF LIFE AND EXPIRY DATE OF CROP PROTECTION PRODUCTS (march 21) provides clear guidance on the term 'ambient' and the temperature control.

Considering that different (high) temperatures may have an impact on the reactivity of the biocidal product, clarification is needed how strict the temperature (control) should be taken into consideration when evaluating the long-term storage study.

Since there is no definition of the term ambient temperature, it is up to the applicant to determine which temperature variations to use. The BPR guidance specifies that the technical monograph is the leading guidance, but other guidance can also be used. It was proposed to agree on a definition for 'ambient temperature'. Several working group members reported that they usually receive tests in the range of 18-25 degrees. However, it was noted that flexibility may be needed to cover different temperature zones and storage conditions. In the technical monograph different ranges for several temperature zones are described.

It was suggested that in general the monograph should be followed and if an applicant deviates from the monograph a justification is required.

Annex 1 - List of attendees registered for the meeting

Country	Members of WG
Austria	Colson Jerome
Austria	Ghobrial Michael
Belgium	Burmistrova Anastasia
Belgium	Ceusters Christiaan
Belgium	Dang Thy Minh-Dung
Belgium	Fauconnier Steven
Belgium	Herremans Yannick
Belgium	Leroy Celine
Switzerland	Aeschbacher Michael
Switzerland	Courdouan Merz Amandine
Czech Republic	Vlasak Martin
Germany	Mühle Ulrike
Denmark	Erlingsson Natja
Denmark	Domino Katrine
Denmark	Jespersen Cindy
Estonia	Vallikivi Imre
Greece	Gatos Panagiotis
Greece	Maragkou Niki
Greece	Tzanetou Evangelia
Spain	Cano David
Spain	Escalada Jesus
Finland	Vuorensola Katariina
France	Azazna Djamil
France	Bujard Thomas
France	Lutz François
France	Six Thérèse
France	Weber Philippe
Italy	Cataldi Lucilla
Latvia	Igaune Ieva
The Netherlands	Kruidhof Sabine
The Netherlands	Huizing Tjaart-Jan
Norway	Helgerud Trygve
Norway	Stave Sekkenes Marianne
Poland	Huszał Sylwester
Poland	Rawska Agnieszka
Portugal	Borges Teresa
Slovenia	Velikonja Bolta Špela
Sweden	Alpe Mia
Sweden	Johansson Anh
Sweden	Österwall Christoffer

Slovakia	Porubiak Michal

ECHA staff
Krebs Bernhard (Chair)
Glans Lotta
Matthes Jochen

Company	Agenda item	Observer
Evonik Nutrition & Care GmbH	7. 6 E-consultation on BPF containing Ampholyt	Hall Caroline Fender Michael
Ercros S.A.	7.5 Chlorine dioxide generated in situ from sodium chlorite	Gracia Francisco Olaizola Aratz
CHRISTIANSEN SARL	9.1 UA Christiansen LD Bednet	Tilling Anne Fleuren Rob
ARCHE Consortia	9.2 UA Arche Chlorine	Jansen Leen Ngo Linh-Dan
ARCHE Consortia	9.3 UA ARIEL Chlorine Professional System 5	Aelbrecht Hilde Van Belle Ellen

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
CEFIC	Van Berlo Boris

WG-I-2021

Final minutes

8 June 2021

Minutes of Efficacy WG-I-2021

18, 23 and 25 March 2021

Meeting of the Efficacy Working Group of the Biocidal Products Committee

Efficacy Working Group

1. Welcome and apologies

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

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

2. Administrative issues

SECR gave brief information on the administrative issues.

3. Agreement of the agenda

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

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

The Chair invited all members to declare any potential conflict of interest to the agenda items. None was declared.

5. Minutes

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

6. Discussion of active substances – 18 March 2021

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

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

7. Discussion of Union Authorisations – 18 March 2021

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

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

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

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

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

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

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

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

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

8.1. Vol. II, Parts B+C – PT1-5

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

The major WG agreements are briefly summarised below:

Room disinfection/automated airborne disinfection of surfaces in PT2:

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

Textile disinfection in PT 2

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

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

8.2. TAB proposals

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

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

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

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

Please refer to the confidential minutes

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

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

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

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

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

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

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

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

8.4 Requirements for insecticide and repellent treated articles (SE)

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

9. AOB

9.1. Other information & lessons learned

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

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

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

Please refer to the confidential minutes.

List of Attendees

Efficacy Working Group I-2021

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

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

Environment WG-I-2021

Final minutes

4 June2021

Minutes of Environment WG-I-2021

24-25 March 2020

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 47 participants present, of which 8 were core members, 30 flexible members, 1 rapporteur and 4 advisers. Four representatives from accredited stakeholder organisation were present at some agenda items. Applicants were registered for their specific substance discussions.

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.

2. Administrative issues

The WGs membership is being reviewed: new nominations will be possible only when an existing member resigns, and additionally during January. The role as an Advisor is preferred if used only to have access to documents and only occasional participation in WG meetings.

The Interact tool will be used for WG meetings. The tool is best used with Firefox. From WG-II-2021 onwards, also meeting documents will be shared in Interact and access will be granted also for advisors and rapporteurs. In Interact, please ignore the given timing: it is a mandatory field but has to be filled in much before there is clarity on the timing. The brief presentation on Interact is available to members and Associated Stakeholder Organisations in S-CIRCABC:

> Path: /CircaBC/echa/BPC-WG/Library/Non-confidential/09. General information and procedural documents/Interact training
>
> https://webgate.ec.europa.eu/s-circabc/w/browse/dd9cdb21-66bc-45c6-8d6a-856c1dc8bf67

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-IV-2020

The minutes were agreed without further changes.

6. Discussion on active substances

6.1 L-(+)-Lactic acid (DE) PT 06

One open point was discussed with regard to the application of the EPM for ionisable substances to derive $PNEC_{sed}$ and $PNEC_{soil}$ from $PNEC_{water}$. The point was agreed in line with previous PTs assessed for the same (anionic) substance and the case can proceed to the BPC.

Actions:

- **SECR** to consider if further actions are needed with regard to the EPM in view of the renewal of ionisable active substances.

6.2 Post-approval data for OIT (FR) PT 08

The FR eCA has tabled two questions to the working group resulting from the post-approval data received. The working group concluded on both and also on applicability of the conclusions on other PTs of OIT being assessed by France (PT 6, 7, 9, 10, 11, 13). The case OIT (FR) PT 08 can proceed to the BPC.

7. Discussion of Union Authorisation cases

7.1 UA for a product containing Permethrin - PT 18 (DK)

Two points were discussed but not agreed since not in the remit of the ENV WG. The points will be taken up at BPC level.

Actions:

- Follow up of RMM and general manufacture discussion at **BPC** level.

7.2 UA for product containing active chlorine released from chlorine – PT 2, 5 (BE)

One point was discussed but not agreed since not in the remit of the ENV WG. The point will be taken up at BPC level.

Actions:

- Follow up of RMM discussion at **BPC** level.

7.3 UA for product containing active chlorine released from sodium hypochlorite – PT 2 (BE)

There was not open point for discussion.

7.4 Outcome of case-specific e-consultations

The outcome of three e-consultations was discussed and agreed.

Actions:

- **SECR** to check with TOX WG the status of the discussion on toxicological relevance of metabolites in groundwater.

8. Technical and guidance related issues

8.1 Guidance on Pollinators - status update

SECR informed on the status of the guidance development.

8.2 TAB database entries - open questions

SECR presented TAB entries which needed further discussion following the first commenting round. The agreed TAB entries are provided in **Annex 1** for confirmation by WG members

ENV TAB 183 - Summing up tonnages of different applicants during active substance approval

The TAB 183 was discussed/agreed for PT 6. Now it is presented as a general item. This would mean that tonnage data from an active substance need to be summed up for each PT/AS combination. For disinfectants it seems to be impossible and might be contradictory to the currently used environmental emission estimation. Shall this entry be valid only for PT6? Or for all PTs?

Conclusion: The WG agreed that for all PTs in which a tonnage-based approach is applicable, the tonnage of two or more applicants should be summed up for the single uses assessed via a tonnage-based approach. It should be noted the focus here is on single uses, not on aggregated exposure assessment.

The risk is usually assessed separately for each sub-scenario (i.e. formulation phase/application phase). Does this TAB apply for each sub-scenario?

Conclusion: It was agreed that it applies to each sub-scenario, since the topic is summing up the tonnages of two or more applicants for single uses and not aggregated exposure assessment.

How do we sum-up in the sub-scenario where a value from a pick list included in the ESD is used instead of the tonnage provided by the applicant? Are these pick list values also to be aggregated?

Conclusion: The question is related to the CIP scenario in PT4 where an annual tonnage of AS per plant is assumed. This scenario is a site-specific scenario and not a tonnage-based approach in the classical sense and the WG agreed that it is therefore exempted from the summing up of tonnages.

If the use concentrations are different among applicants, how to calculate the maximum tonnage?

Conclusion: The WG agreed that this point is not relevant, since use concentrations are not applicable in the tonnage-based approach, since the tonnage of the AS in the EU is the starting point for the calculations, independent of the use concentration.

Post WG meeting note: ES came back to SECR and pointed out that in PT 6 for the formulation step of the end-product use concentrations are relevant. Further discussion on these specific scenarios is needed.

If the maximum value with a safe use is given to the applicants, how are they supposed to change their tonnage productions based on that figure?

Conclusion: The WG noted that not the tonnage of the different applicants should be adapted but the RMMs that can be used the minimise the release, as it is done also under REACH (see ERCs and SPERCs).

The TAB refers to two applicants. Does the working group agree that the TAB is valid for more than two applicants? Does the working group agree to change the wording from "only two applicants" to "two or more applicants"?

Conclusion: Covered by item 1.

Action:

- **SECR** to prepare final TAB entry and add it to the minutes for review.
- **SECR** to check with LAU the final TAB entry before the TAB entry is published.

ENV TAB 226 Ants – outdoor (large buildings): Spot treatment on terraces

It was proposed to change the text of the ENV TAB 226, merging it with an expired entry. The WG agreed to keep the original text as agreed at AHEE-5.

NL requested post-WG that the following explanation should be noted in the minutes: It was noted in the meeting that for assessment of use on terraces of large buildings in urban areas the perimeter scenario should be used (taking into account emission to the STP) and that for use on terraces of large buildings in rural areas the terrace scenario for households (with emission to the soil) should be used.

Clarification on the PECsoil used for derivation of porewater concentration, in the following cases:

i) STP sludge application

ii) Manure application

iii) Direct release to soil

In case of STP sludge application, in both grassland and agricultural soil, the derivation of porewater concentrations is based on a PEC soil averaged for 180 days after 10 years of sludge application (180d TWA PECsoil). This is specified in the Biocides Guidance Vol IV Part B+C, e.g. on p.93. However, on the same p.93 of the Guidance, the equation for deriving the concentration in the porewater from the PECsoil is provided with the indication (in footnote) that "the worst-case agricultural PEC value for arable land should be used". As the 180d TWA PECsoil after 10 years of sludge application is not the worst-case agricultural PEC, there is a contradiction in the Guidance, which we propose to clarify.

In case of manure application, in both grassland and agricultural soil, the derivation of porewater concentrations is based on an initial PEC soil after 10 years of manure application and taking degradation into account during the first nine years.

In case of direct releases, the derivation of porewater concentrations is based on initial PECsoil values.

Conclusions:

The WG agreed that for the PECgw calculation for STP sludge application, the 180d TWA PECsoil (the worst case from agricultural soil or grassland) after 10 years of sludge application should be used.

The WG agreed that also for manure/slurry application on agricultural soils (arable land and grassland) the 180d TWA PECsoils should be used for the PECgw calculations. PECsw: It was provisionally agreed to use the PECgw based on the 30d TWA PECsoil to calculate the PEC in surface water (to be confirmed during the TAB entry commenting).

For direct releases, the PEC as it is currently calculated in the different ESDs (e.g. PT 8, PT 14, PT 19) should be used as basis for the PECgw calculation, no transfer to a 180d TWA PECsoil is needed.

Action:

- **SECR** to correct the footnote text and provide a proposal for the revised text and harmonised equations together with the TAB entry.

Time frame for the assessment of PT 11 products for the Preservation of wood treatment solutions (in the wood treatment systems)

The WG agree on the proposed conclusion (see Annex 1) on the time frame for the assessment of PT 11 products for the Preservation of wood treatment solutions (in the wood treatment systems).

Overall action:

- **WG members** to confirm the revised TAB entries **provided in Annex 1 below**.

8.3 Development of Chesar platform – status and open questions

SECR presented the status of the development or CHESAR platform. SECR also informed that soon a call of interest to join the CHESAR platform Stakeholders' group would be launched and encouraged WG members and stakeholders to join this group.

SECR further presented proposals for the temperature correction for vapour pressure, water solubility and Henry's law constant in the future CHESAR platform. The proposals attempt to streamline the practice of EUSES.

The WG agreed to the proposals for the implementation of the temperature correction for vapour pressure, water solubility and Henry's law constant.

Action:

- **SECR** to check accuracy in the background calculations when the temperatures in Celsius are transferred to Kelvin (does rounding occur?).

8.4 CEPE study: semi-field leaching tests for PT 7

CEPE presented the semi-field leaching tests performed for PT 7 and its results. Also presented a comparison with laboratory leaching. CEPE concluded having identified worst cases coatings and has identified a method that usually overestimates the leaching rates, and which could be used as worst case. With these results CEPE aims to reduce future PT 7 testing.

Action:

- **SECR** will set up an e-consultation with the questions from CEPE to the WG members (provided together with the presentation as background). The e-consultation will also include open points from PT 8 expert group in 2020.
- **CEPE** will be invited to participate in the e-consultation.

8.5 *The item was moved to 7.4 since it was related to a substance case*

8.6 Open questions regarding PT 3 and PT 18

8.6a: PT 18 manure and PT 3 animal housing – new application ways and release fractions

SECR presented seven questions on additional ways of application of biocidal products in animal housings, under PT 18 and PT 3, and the respective release fractions.

The following was agreed by the WG:

1. On "Larvicides" and "Sprinkling" in PT 18: the release fractions for "Larvicides (3)" (animal categories 1,2,3,4,5,6) shall be the same as those defined for "All insecticides (1,2,4)", i.e. release to slurry = 0.9.
2. On "Larvicides" and "Sprinkling & Bait" in PT 18: since bait application is not relevant for larvicides, no default value is needed for the combined sprinkling and bait application.

Action:

- **SECR** to prepare a TAB entry on the revised table and to add a note in the entry that bait application is not relevant for larvicides.

3. On "Fumigation" in PT 18:
    a. Fractions: The WG agreed to revise Table 5.4 [from the OECD ESD n.14 PT 18 (2006)] and add it in the TAB with the following adaptations: the column on Aerosol will be re-named to Aerosol/Fogging and the fraction released to slurry will be corrected to 0.34 (calculated by taking into account the amount of 98% settling on the floor times the fraction of 0.35 currently in the table for slurry). In addition, a column for fumigation will be added with a fraction released to slurry of 0.007 (calculated by taking into account the amount of 2% settling on the floor times the fraction of 0.35 assumed for slurry).
    b. Release via air and deposition to soil: This release pathway should be assessed for fumigation, since it is the major release pathway.

Action:

- **SECR** to assess if equation 44 and subsequent equations of Vol. IV Part B+C can be used for the calculations and to add an additional sentence to the TAB entry proposed for that item.
- **SECR** to set up a thematic discussion with experts from the member states whether other models are known that are better suited to calculate this release path.
- **SECR** to prepare TAB entry, WG members to revise proposed adapted table with the minutes.

4. On "Foaming" in PT 18: the WG agreed to use the same release fractions as defined for spraying.
5. On "Fogging" in PT 3: the WG agreed to use the revised release fractions (see point 3 above) for aerosols from the OECD ESD n.14 PT 18 (2006). Whereas for hatcheries, the default values as provided in the ESD for PT 3 should continue to be used.
6. On "Foaming" in PT 3: the WG agreed that the release fractions for spraying from the OECD ESD n.14 PT 18 manure (2006), Table 5.4, can be used.
7. On "Fumigation" in PT 3: the WG agreed that fumigation should be considered also for PT 3, using the agreed fractions for PT 18 (see point 3 above). Regarding the default volume, the values provided in the OECD ESD n.14 PT 18 (2006) for fogging should be used.

Overall action:

- **WG members** to confirm the revised TAB entries **provided in Annex 1 below**.

8.6b: Extension of TAB entry 162 - Calculation of the initial concentration in soil after four manure applications taking degradation processes in soil into account

DE presented two options to overcome the conservative estimations of environmental exposure in the grassland scenario:

1) Through the refinement of the equation to calculate the concentration of the a.s. in soil after four manure application events considering all prescribed a.s. applications by taking degradation in soil into account. This would mean an extension of TAB entry 162 to cover degradation.

2) Through a modified calculation method of the number of biocidal product applications during manure storage period for application on grassland (Napp-manure-gr).

   If Tbioc-int ≥ Tgr-int, then Napp-manure-gr = 1
   If Tbioc-int < Tgr-int, then Napp-manure-gr = ROUND [(Tgr-int/Tbioc-int), (1)],
   If Nlapp-grass x Napp-manure-gr > Napp-prescr, then Napp-manure-gr = Napp-prescr/Nlapp-grass, (2)

DE proposed to follow option 2), to which the WG agreed.

Furthermore, DE briefly presented the proposal to deal with b.p applications for which Tbioc-int ≥ Tgr-int. It was proposed to replace the first condition of the method indicated above by the following:

If Tbioc-int ≥ Tgr-int, then Napp-manure-gr = Napp-prescr/Nlapp-grass

Action:

- **NL** to add a third "if" option in the Addendum (2020) and **SECR** to delete TAB entry 162 (see option 2 above).
- **NL** will prepare together with **DE, CH and SECR** a proposal for adding explanations on Napp-manure-gr in section 2.3.1 in the Addendum. Also, the proposal on how to deal with b.p applications for which Tbioc-int ≥ Tgr-int should be taken into account (which was confirmed by WG members but additional time for revising is allowed – comments can then be provide when the revised Addendum is adopted by the **WG**).
- **ASOs** will be added in the consultation.

8.6c: Considerations of b.p. applications in slurry/manure storage systems in exposure assessment

DE presented a paper raising two major questions:

1) The OECD ESD PT 18, No. 14 (2006), Appendix 5 distinguishes between slurry ("wet") and manure ("dry") storage systems depending on the animal (sub)category. Sometimes, product applications may talk about "indoor" vs. "outdoor" but the ESD is not clear whether the description "indoor" also means manure/slurry storage systems below the actual housing area or in a separate building close to the stable. DE was seeking clarification on what areas to use for those indoor/outdoor categories which are not in the ESD.

2) A second question was related to the use of slurry lagoons in the EU. DE sought the views of the MS on whether slurry lagoons should be considered relevant in the EU and thus, whether the environmental exposure assessment for use description "outdoor" should be carried out with the available worst-case values for surface areas (defaults as provided in Appendix 5 of ESD PT18 No. 14).

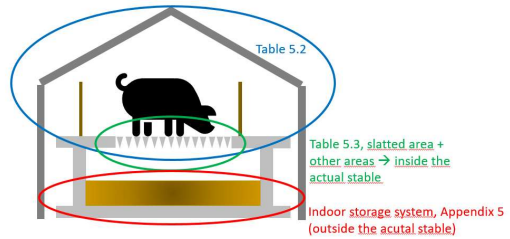
On the <u>first question</u> DE made the following proposals, all agreed by the WG:

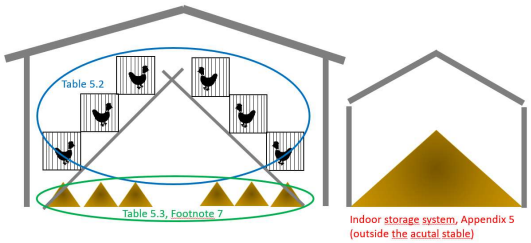
In case of b.p. use descriptions "under the slatted area" or "manure storage systems below the stables" or "indoor":

- For animal (sub)categories 1-7, 10, 13-15 the surface area of rectangular slurry tanks should be used for the assessment (defaults as provided in Appendix 5 of ESD PT18 No. 14).
- For animal (sub)categories 8, 9, 11, 12, 16-18 the surface area of manure heaps should be used for the assessment (defaults as provided in Appendix 5 of ESD PT18 No. 14).

For manure heaps (animal (sub)categories 8, 9, 11, 12, 16-18) both indoor and outdoor storage systems should be considered in the environmental exposure assessment. Therefore, in case of b.p. use description "dry storage" or "manure heaps", the assessment is independent of the use description "indoor" or "outdoor".

The use description should be distinguished from those b.p. applications described in Table 5.3. In Table 5.3 defaults areas for manure storage inside the housings are mentioned like e.g. manure belts which are in the stable where the animals are kept (please see the following pictures):





The second question was discussed but remains open.

Action:

- **WG members** will collect further information.
- **SECR** will set up an e-consultation to collect WG members feedback on the use of slurry lagoons in the EU.
- **SECR** to prepare a TAB entry on the agreements reached and **WG members to revise the draft TAB entry** proposed in Annex 1 below.

9. AOB

9.1 Other information & lessons learned (SECR)

E-consultations and early WG discussions:

SECR noted that the members from different WGs and different MSCAs have different understandings of what these tools are intended for. SECR clarified the concepts indicating

that an e-consultation should be understood as a measure where a MSCA seeks advice from (other) experts. The outcome of an e-consultation is advice, not a conclusion, and if needed, the MSCA can seek for a WG discussion.

In an early WG discussion, conclusions are possible within the WG mandate. The conclusions should however be provisional if the final conclusion requires seeing the complete assessment (e.g. whether the data package is complete), or if general discussions are on-going (e.g. guidance is under development), or if a policy/regulatory decision is needed and/or the discussion is ongoing e.g. at CA or CG meetings. SECR noted that for all these cases, the WG can make case specific conclusions in a regular WG discussion but not in an early WG meeting.

SECR further noted that no conclusion will be made in an early WG discussion where the WG does not have the mandate:

- Information to be requested from the applicant
- CLH for active substances
- Policy related issues
- Risk management measures

If these topics are discussed at the WG, the outcome should be considered as advice coming from individual experts.

Other information:

Provisional timing of coming WG meetings

- AHEE-6 is postponed to autumn 2021 => depending on availability of items for discussion – urgent topics can be added to ENV WG meetings.
- WG-II-2021 ENV session planned 3-4 of June 2021 and 9-11 June 2021 [*updated post WG meeting*]
- There is always a possibility of additional ("extraordinary") ad hoc WebEx meetings, if needed.

All meetings organised by ECHA will remain virtual at least until the end of September 2021.

Harmonised LoEP for pyrethroid metabolites

Update of 1R-trans Phenothrin CAR in 2020: New ENV fate data on 1R-trans Phenothrin were discussed at ENV WG-III-2020 and BPC-37, relevant studies for the derivation of DT50 values for the metabolite "PBacid" (Hiler, 2016, and Dubrey, 2016) were presented. The PBT section of the CAR was updated, however, no re-calculation for the exposure assessment was performed in the CAR revision.

Update of the data matrix: Current update restricted to the revised P-conclusion for w/s, already agreed by the WG in 2020 (no need of e-consultation)
The revision of the exposure part will be performed at the renewal stage of 1R-trans Phenothrin, SECR will send a notice to the ENV WG by email.

In-situ Recommendations - progress

The next Task Group meeting is scheduled for 16 April 2021:

- CA_July19_Doc.4.1 – updated in March CA meeting – new version: CA-July19-Doc.4.1-Final (As amended by CA-Dec20-Doc.4.14 and CA- March21-Doc4.10)
- This new version includes a revision of the case-type 3 as recent technical developments were no longer in line with the previous description
- At the CG-45 meeting a document for In situ – washing machines CG-45 e-c In situ - washing machines FINAL.pdf was agreed

TAB – consultation of CG on type of entry for BP

The current date of applicability based on type of entry in the TAB is as follows:

	Applicability of the TAB entry	
Type of entry in the TAB	**(A) for active substance approval**	**(B) for product authorisation**
a) Editorial changes of the existing guidance	As of the reference date	As of the reference date[6]
b) Clarification/interpretation of the existing guidance (clarification /explanation)	As of the reference date	As of the reference date[6]
c) New guidance as new technical scientific advice is given which triggers new data requirements	six months after the reference date[7]	2 years after the reference date[6,8]
d) New guidance as new or updated technical scientific advice is given in order to have a harmonised approach on how the assessment should be done (without new data requirements)	six months after the reference date[7]	2 years after the reference date[6,8]
e) New guidance not triggering new data requirements where: • no guidance was available at all for a certain issue • new guidance is correcting major mistakes of former guidance • new guidance is considerably more reliable than former guidance.	As of the reference date[7]	2 years after the reference date[7,8]

The CG was asked to agree on "rules" when to assign a type of entry b) and when d), based on ENV TAB entries. There was a written procedure and then discussion at CG 45. A follow-up newsgroup was opened since the item could not be concluded. ECHA will apply the results of the consultation and will update the TAB accordingly.

Lessons learned:

Commenting of TAB entries
When **commenting** new TAB entries please be very specific with regard to proposed changes:

- e.g. do not add comments like "this should be further clarified in the text" but provide instead proposals for clarifications directly in the TAB text in track change modus
- Due to more frequent TAB releases we will ignore unspecific comments in the future

Requests for further explanations in TAB entries

- The TAB entry reflects conclusions as noted during WG meetings - if they are not considered sufficient, please react during noting the conclusions at the WG meetings or during commenting of the minutes so that they are sufficiently explanative.
- Alternatively, propose an explanation when commenting the new TAB entry.

9.2 Meeting the timelines: alternative ways of working (SECR)

SECR presented three possibilities for alternative ways of working. The presentation is available to MSCAs in S-CIRCABC and the points will be further raised in a survey after the WG meeting.

Revision of accordance check

This action is considered by ECHA because of the relatively high number of failed accordance checks, where similar issues are often encountered. The action would be to ensure that these common issues would be better known to enable the eCAs to address these before submission.

Piloting co-rapporteurship

SECR proposed a possible approach where the eCA would be supported by a co-rapporteur, in principle replacing part of the current peer review by all MSs with the approach where one MS would take a major role.

Several critical comments were made regarding this proposal, seeing that the co-rapporteurship could limit the scope and reduce the currently available diversity of views, which was seen as a strength of the system.

A discussion will take place at the next BPC, where a pilot may be proposed.

Removing ad hoc follow-up

SECR proposed removing ad hoc follow-ups as a time-consuming procedure that may in some cases prevent concluding at the WG meeting.

Instead of an ad hoc follow-up, where technical and scientific issues remain undecided at WG meeting, the issue would be solved based on the assessment by the eCA. A commenting period on the updated CAR/PAR still takes place before the BPC meeting, allowing a peer-review, although less detailed than in an ad hoc follow-up. This might result in technical and scientific issues being open at the BPC, which would in practice mean relying on the eCA proposal, because the BPC might not be able to deal with such technical issues.

Some of the members agreed to remove ad hoc follow-ups, while others considered that the important issues left open at WG should still be solved at the technical level before the BPC. The members agreed that a shift has already taken place, reducing ad hoc follow-ups to those cases where it is really seen necessary. Specifically, the use of early WGs helped to prevent ad hoc follow-ups

Appendices:

Appendix 1: List of TAB entries for confirmation by WG members

TAB entry proposal related to item 8.2

ENV 183 Summing up of tonnages of active substances in standard tonnage-based emission scenarios during the active substance approval, Version 1 (WG-III-2020; WG-I-2021)

This TAB entry applies for all standard tonnage-based emission scenarios and for PT 6 also for tonnage-based scenarios in any sub-categories. An active substance approval for a specific product-type is not an individual application but an approval of the substance in the EU and should consider all biocidal uses in one product-type. Therefore, the tonnages of all applicants (per the same use) should be summed up when tonnage-based scenarios are used. Note that this TAB entry does not cover aggregated exposure summing up emissions from different PTs.

A specific procedure for summing up of tonnages in case of only two applicants was agreed in order to protect the confidentiality of the tonnage of the single applicants:

- The eCA sums up the tonnages in the confidential part of CAR which by no means should be shared with applicants
- The eCA further calculates in the non-confidential CAR the maximum tonnage that would still result in a safe use (PEC/PNEC is just below 1)
- In the confidential part of the CAR, this maximum tonnage is compared to the sum of applicants' tonnages and a conclusion on a safe/non-safe use is drawn
- Only this conclusion (safe/non-safe use) is then reported in the non-confidential part of the CAR.

For more than two applicants, the procedure agreed for "only two applicants" can be followed but might be less relevant as it is more difficult to back-calculate the tonnage of one applicant.

In case an unacceptable risk is identified, suitable RMM to minimise the emission can be used.

This TAB entry is not applicable to biocidal products.

ENV 226 Ants – outdoor (large buildings): Spot treatment on terraces

No additional scenario for terraces in the case of large buildings is needed, since the perimeter scenario represents the worst case (for emission path via STP). In case an applicant intends a product only to be applied on terraces, the existing terrace scenario (for households) could be used as surrogate.

ENV 237 [new] Clarification on the PECsoil used for derivation of porewater concentration equal to PECgw

STP sludge and manure application: for both, grassland and arable land, the derivation of porewater concentrations should be based on a PEC soil averaged for 180 days after 10 years of sludge/manure application (180d TWA PEClocalsoil).

In case of sewage sludge application on agricultural soils, this is specified in the Biocides Guidance Vol IV Part B+C, p.93. It is noticed that in Table 9 on page 92, line 2, the term $PEClocal_{agr.\ soil}$ should be corrected to $PEClocal_{arable\ soil}$.
The footnote 16 on the page 93 as well as further chapters of the Guidance (e.g. chapter 2.3.7.6) need to be further clarified, when the guidance will be revised in the future. It is indicated in the footnote that "the worst-case agricultural PEC value for arable land should be used". This refers in fact to Table 9 on page 92, where both lines 2 and 3 are related to the PEC in soil for agricultural soils, where **the worst case in arable land** (line 2) compared to grassland (line 3) should be used to further assess PECgw (porewater) subsequent to sewage sludge application on agricultural land.

In case of manure/slurry application on agricultural soils: for both, grassland and arable land, the derivation of porewater concentrations should also be based on 180 d TWA PECsoils. For the PEC in surface water, after drainage or run-off from soil, the PECgw based on the 30d TWA PEClocalsoils in grassland and arable land shall be used to calculate PECsw [***to be confirmed during the TAB entry commenting***].

Direct releases to soil: the derivation of porewater concentrations is based on the initial PEClocalsoil values (Table 9, line 1). For direct releases, the PECsoil as it is currently calculated in the different ESDs (e.g. PT 8, PT 14, PT 19) should be used as basis for the PECgw calculation (porewater), no transfer to a 180d TWA PEClocalsoil is needed.

ENV 232 [new] Time frame for the assessment of PT 11 products for the Preservation of wood treatment solutions (in the wood treatment systems)

A service-life of 365 days should be used to conduct the exposure assessment for PT 11, covering wood treatment systems. It is assumed that 100% of the active substance applied is leached out within the 365 days, in case no leaching data is available.

Additionally, a short-term assessment of 30 days (assuming 50% leaching if no leaching data is available) should be conducted. RCRs derived for both assessment periods should be considered for decision making.

TAB entry proposal related to item 8.6

ENV 233 [new] Changes to Table 5.4 from OECD ESD n.14 PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (2006)

The following tables show the changes introduced to Table 5.4, p.40 and 41, from the *OECD ESD n.14 PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (2006)*. All other values not included here remain unchanged and the *OECD ESD n.14 PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (2006)* should be consulted.

Excerpt from *Table 5.4*, p.40, modified and showing changes in different colour:

Changed/new values are shown in green font:

- For application by Aerosol/Fogging the fractions released (to slurry, manure, and wastewater) were corrected taking account that 2% of the releases will go to the air and 98% will settle (OECD ESD n.14 PT 18 (2006), p.29). This results in e.g.

application of a larvicide by aerosol/fogging – fraction emitted to slurry: 0.98x0.34=0.343.

- For the new application by Fumigation the fractions defined in the ESD for Aerosol were used as a starting point; was also considered that 98% of the emissions are emitted to air (OECD ESD n.14 PT 18 (2006), p.30). This results in e.g. application of a larvicide by fumigation – fraction emitted to slurry: 0.02x0.34=0.007; fraction emitted to air: 0.98x0.34=0.343.

Emissions to air were added for application by fumigation and are shown in **green bold font**.

Cells highlighted in yellow: the b.p. applied by aerosol/fogging or fumigation is applied to an empty animal housing, i.e. without manure; nevertheless, slurry may be present under the slatted floor. Therefore, was considered that the emissions of b.p. will reach the slurry and not the manure and the emissions previously indicated to manure are now indicated to slurry.

- = *not applicable* (as indicated in the ESD)

Excerpt from *Table 5.4*, p.40

Category (cat-subcat)	Type of biocide (bioctype)	Spraying / Foaming (1)			Aerosol / Fogging (2)				Smearing (3)			Fumigation			
		Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)	**Air**	Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)	**Air**
Livestock															
Cattle, Pigs, Veal calves															
(1,2,3,4,5,6)	All insecticides (1,2,4)	*No further changes*			•	•	0.343	*0.02*	*No further changes*			•	•	0.007	**0.98**
(1,2,3,4,5,6)	Larvicides (3)				•	•	0.343	0.02				•	•	0.007	**0.98**
(19)	Larvicides (3)				•	•	0.98	0.02				•	•	0.02	**0.98**
Poultry															
Battery cage															
-conveyor belt with aeration															
(8)	All insecticides (1,2,4)				•	0.098	0.343	0.02				•	0.002	0.007	**0.98**
(8)	Larvicides (3)				•	0.098	0.343	0.02				•	0.002	0.007	**0.98**
(20)	Larvicides (3)				•	•	0.98	0.02				•	•	0.02	**0.98**
-forced drying (deep pit, high-rise)															
(9)	All insecticides (2,4)				0.343	•	•	0.02				0.007	•	•	**0.98**
(9)	Flies (1)				0.343	•	•	0.02				0.007	•	•	**0.98**
(9)	Larvicides (3)				0.343	•	•	0.02				0.007	•	•	**0.98**
(20)	Larvicides (3)				0.98	•	•	0.02				0.02	•	•	**0.98**
-conveyor belt (no aeration)															
(7,10)	All insecticides (1,2,4)				•	•	0.343	0.02				•	•	0.007	**0.98**
(7,10)	Larvicides (3)				•	•	0.343	0.02				•	•	0.007	**0.98**
(19)	Larvicides (3)				•	•	0.98	0.02				•	•	0.02	**0.98**
Free range															
-litter floor (11,12,16,17,18)	All insecticides (1,2,4)				0.245	0.098	•	0.02				0.005	0.002	•	**0.98**
(11,12,16,17,18)	Larvicides (3)				0.245	0.098	•	0.02				0.005	0.002	•	**0.98**
(20)	Larvicides (3)				0.98	•	•	0.02				0.02	•	•	**0.98**
- gratting floor (13,14,15)	All insecticides (1,2,4)				•	•	0.343	0.02				•	•	0.007	**0.98**
(13,14,15)	Larvicides (3)				•	•	0.343	0.02				•	•	0.007	**0.98**
(19)	Larvicides (3)				•	•	0.98	0.02				•	•	0.02	**0.98**

Excerpt from *Table 5.4 (continued)*, p.41, modified and showing changes in red font.

• = *not applicable* (as indicated in the ESD)

To be noted that since bait application is not relevant for larvicides, no default value is needed for the combined sprinkling and bait application.

Excerpt from *Table 5.4 (continued)*, p.41

Category (cat-subcat)	Type of biocide (bioctype)	Sprinkling (1)			Bait (2)			Sprinkling & Bait (3)		
		Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)
Livestock										
Cattle, Pigs, Veal calves										
(1,2,3,4,5,6)	All insecticides (1,2,4)	•	•	0.9	•	•	0.5	•	•	0.75
(1,2,3,4,5,6)	Larvicides (3)	•	•	**0.9**	•	•	•	•	•	•
(19)	Larvicides (3)	•	•	1	•	•	•	•	•	•
No further changes		*No further changes*			*No further changes*			*No further changes*		

ENV 234 [new] Biocidal product applications in slurry/manure storage systems in exposure assessment of PT 18

The *OECD ESD No. 14 PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (2006), Appendix 5* distinguishes between slurry ("wet") and manure ("dry") storage systems depending on the animal (sub)category. Sometimes, product applications may talk about "indoor" vs. "outdoor" but the ESD is not clear whether the description "indoor" also means manure/slurry storage systems below the actual housing area. Therefore, in case of b.p. use descriptions "under the slatted area" or "manure storage systems below the stables" or "indoor" the following should be adhered to:

- For animal (sub)categories 1-7, 10, 13-15 the surface area of rectangular slurry tanks should be used for the assessment (defaults as provided in Appendix 5 of ESD PT18 No. 14).
- For animal (sub)categories 8, 9, 11, 12, 16-18 the surface area of manure heaps should be used for the assessment (defaults as provided in Appendix 5 of ESD PT18 No. 14).

For manure heaps (animal (sub)categories 8, 9, 11, 12, 16-18) both indoor and outdoor storage systems should be considered in the environmental exposure assessment. Therefore, in case of b.p. use description "dry storage" or "manure heaps", the assessment is independent of the use description "indoor" or "outdoor". But the use description should be distinguished from those b.p. applications described in Table 5.3. In Table 5.3 default areas for manure storage inside the housings are mentioned like e.g. manure belts which are in the stable where the animals are kept.

Appendix 2: List of participants

Core members:

- (DE) Daniel **FREIN**
- (DE) Eleonora **PETERSOHN**
- (FR) Stéphanie **ALEXANDRE**
- (FR) Anne **STRACZEK**
- (IE) Helena **JOYCE**
- (NL) Barry **MUIJS**
- (NL) Karlijn **HOLTHAUS -** alternate
- (SI) Petra **MURI**

Flexible members:

- Altmann Dominik (AT)
- Kührer Lukas (AT)
- Brasseur Anne (BE)
- Ceusters Christiaan (BE)
- Leroy Celine (BE)
- A Marca Maria (CH)
- Gyalpo Tenzing (CH)
- Kunz Petra (CH)
- Ahting Maren (DE)
- Loskyll Julia (DE)
- Michaelis Katja (DE)
- Wennermark Henrik (DK)
- De la Flor Tejero Ignacio (ES)
- Martin Vallejo Myriam (ES)
- Ruiz Lopez Elena Fuensanta (ES)
- Hänninen Oskari (FI)
- Pasanen Jaana (FI)
- Penttinen Sari (FI)
- Conroy Kenneth (IE)
- Paskuliakova Andrea (IE)
- De Magistris Isabella (IT)
- Smit Els (NL)
- van Vlaardingen Peter (NL)
- Aamodt Solveig (NO)
- Espevik Randall Marit (NO)
- Haraldsen Terje (NO)
- Podlaska Agnieszka (PL)
- Rzodeczko Helena (PL)
- Konovalenko Lena (SE)
- Molnarova Jana (SK)

Rapporteurs:

- Verstraet Séléné (FR)

Advisors:

- Villumsen Rasmus (DK)
- Convert Yannice (FR)
- Gilson Arthur (FR)

ASOs:

- Garmendia Irantzu (CEFIC representative) – all agenda items except closed ones
- Mason Paul (CEFIC expert)
- Thom Ellen (CEFIC expert)
- Leroy Didier (CEPE)

ECHA chairs and experts

Human Health WG-I-2021

Final minutes

1 June 2021

Minutes of Human Health WG-I-2021

16-18 March 2021

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 59 members or advisers registered, of which 12 were (alternate) core members. One stakeholder representative and two experts were registered. Applicants were registered for their specific substance discussions.

The 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

The WGs membership is being reviewed: new nominations will be possible only when an existing member resigns, and additionally during January. The role as an Advisor is preferred if used only to have access to documents and only occasional participation in WG meetings.

The Interact tool will be used for WG meetings. The tool is best used with Firefox. From WG-II-2021 onwards, also meeting documents will be shared in Interact and access will be granted also for advisors and rapporteurs. In Interact, please ignore the given timing: it is a mandatory field but has to be filled in much before there is clarity on the timing. The brief presentation on Interact is available to members and Associated Stakeholder Organisations in S-CIRCABC:

> Path: /CircaBC/echa/BPC-WG/Library/Non-confidential/09. General information and procedural documents/Interact training
>
> https://webgate.ec.europa.eu/s-circabc/w/browse/dd9cdb21-66bc-45c6-8d6a-856c1dc8bf67

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 draft minutes from WG-IV-2020

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 L-(+)-lactic acid, PT 6 (eCA DE)

The discussion clarified that the dermal NOAEC of 10% should not be considered as a general reference value and applying this value should be justified, noting also the 5% generic concentration limit for classification.

6.2 Sulphur dioxide generated from sulphur by combustion, PT 4; Sulfur dioxide released from sodium metabisulfite, PT 9 – ED Assessment (eCA DE)

Sulfur dioxide was concluded not to meet the criteria for endocrine disruption with regard to human health.

7. Discussion of Union authorisation applications

7.1 UA for product containing Permethrin, PT 18 (eCA DK)

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

Closed session on disinfection by-products

A brief closed session took place to discuss in a general manner the assessment of disinfection by-products (DBP). This discussion was for MSCAs only to allow exchange of confidential information on a large number of applications that are expected to come to peer review during the next year.

The members aknowleded the difficulties in performing a DBP assessment due to the lack of proper data and the guidance covering only PT 2 swimming pool scenarios. It was also noted that the current DBP guidance may not allow concluding on the risks.

The members however considered that a DBP assessment will be necessary for all PTs, but these will aim more at collecting and assessing available information and could be provided as non-agreed annexes provided by the eCA.

For PT 2 swimming pool uses, the members considered that the currently available guidance should be followed.

7.2 UA for product containing active chlorine released from chlorine, PT 2, 5 (eCA BE)

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

7.3 UA for product containing active chlorine released from sodium hypochlorite, PT 2 (eCA BE)

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

8. Discussion of mutual recognition

8.1 Request to ECHA for an opinion pursuant to Articles 36(2) and 38 of the BPR

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

9. Technical and guidance related issues

9.1 Update on guidance development

SECR presented the current status of guidance documents. The document is available in S-CIRCABC to members and associated stakeholder organisations.

9.2 Proposal for a new TAB entry on local effects

The proposed entry was not supported.

9.3 Review of TAB

The discussion concerned SECR proposals to remove obsolete TAB entries and bring the TAB up to date. The WG agreed to:

- merge entries #1 and #42,
- merge entries #9, #10 and #11,

- modify entries #16 and #45, and
- remove entries #6, #7, #8, #20, #47, #48 and Appendix 1.

9.4 Dermal absorption of rodenticides

The WG agreed on the two documents provided by DE, regarding the assessment methodology for dermal absorption of anticoagulant rodenticides. SECR noted that the applicability rules for active substances and products apply, but it was considered that the guidance could already be used where the evaluating MSCA and applicant agree on this.

The documents will be published in the public S-CIRCABC site[1] once finalised.

10. Any other business

10.1 Other information & lessons learned

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

E-consultations and early WG discussions

SECR noted that the members from different WGs and different MSCAs have different understandings of what these tools are intended for. SECR clarified the concepts indicating that an e-consultation should be understood as a measure where a MSCA seeks advice from (other) experts. The outcome of an e-consultation is advice, not a conclusion, and if needed, the MSCA can seek for a WG discussion.

In an early WG discussion, conclusions are possible within the WG mandate. The conclusions should however be provisional if the final conclusion requires seeing the complete assessment (e.g. whether the data package is complete), or if general discussions are on-going (e.g. guidance is under development), or if a policy/regulatory decision is needed and/or the discussion is ongoing e.g. at CA or CG meetings. SECR noted that for all these cases, the WG can make case specific conclusions in a regular WG discussion but not in an early WG meeting.

SECR further noted that no conclusion will be made in an early WG discussion where the WG does not have the mandate:

- Information to be requested from the applicant
- CLH for active substances
- Policy related issues
- Risk management measures

If these topics are discussed at the WG, the outcome should be considered as advice coming from individual experts.

Next WG meetings

SECR informed of the provisional timing of the next meetings:

- 31 May - 11 June 2021 (exact days to be established)
- 13 - 24 September 2021 (exact days to be established)

All meetings organised by ECHA will remain virtual at least until the end of September 2021.

10.2 Meeting the timelines: alternative ways of working

SECR presented three possibilities for alternative ways of working. The presentation is

[1] Path: /CircaBC/echa/Documents agreed at BPC WG meetings/Library/Human Health WG; direct link: https://webgate.ec.europa.eu/s-circabc/w/browse/85748090-25b8-4c7a-9184-2c7b7c0a645b

available to MSCAs in S-CIRCABC.

Revision of accordance check

This action is considered by ECHA because of the relatively high number of failed accordance checks, where similar issues are often encountered. The action would be to ensure that these common issues would be better known to enable the eCAs to address these before submission.

Piloting co-rapporteurship

SECR proposed a possible approach where the eCA would be supported by a co-rapporteur, in principle replacing part of the current peer review by all MSs with the approach where one MS would take a major role.

Several critical comments were made regarding this proposal, seeing that the co-rapporteurship could limit the scope and reduce the currently available diversity of views, which was seen as a strength of the system. It was also mentioned that human exposure assessment (HEAdhoc) and dietary risk assessment (ARTFood) might be especially affected.

A discussion will take place at the BPC, where a pilot may be proposed.

Removing ad hoc follow-up

SECR proposed removing ad hoc follow-ups as a time consuming procedure that may in some cases prevent concluding at the WG meeting.

Instead of an ad hoc follow-up, where technical and scientific issues remain undecided at WG meeting, the issue would be solved based on the assessment by the eCA. A commenting period on the updated CAR/PAR still takes place before the BPC meeting, allowing a peer-review, although less detailed than in an ad hoc follow-up. This might result in technical and scientific issues being open at the BPC, which would in practice mean relying on the eCA proposal, because the BPC might not be able to deal with such technical issues.

Some of the members agreed to remove ad hoc follow-ups, while others considered that the important issues left open at WG should still be solved at the technical level before the BPC. The members agreed that a shift has already taken place, reducing ad hoc follow-ups to those cases where it is really seen necessary.

Annex 1

Human Health WG attendees

Core/Alternate members
MIKOLAS Jan (CZ)
HERRMANN Kristin (DE)
HOLTHENRICH Dagmar (DE)
GUENTHER Isabel - Alternate (DE)
ARAPAKI Niki (EL)
NIKOLOPOULOU Dimitra (EL)
MAXIMILIEN Elisabeth (FR)
AUBIN Aurelie – Alternate (FR)
BARRON Thomasina (IE)
BREEN Alan (IE)
WELTEN Angelique – Alternate (NL)
LEŠER Vladka (SI)
Rapporteurs
CEUSTERS Christiaan (BE)
LEROY Celine (BE)
THYEBORG LIND Helene (DK)
Flexible members
HAUZENBERGER Ingrid (AT)
HOELZL Christine (AT)
HERREMANS Yannick (BE)
HOUAMED Anis (BE)
GOLDINGER Daniela (CH)
GRÜNIG David (CH)
ROSSIER Nadine (CH)
RUSCONI Manuel (CH)
SEDLACKOVA Viktorie (CZ)
KLUTZNY Saskia (DE)
RIME Soyub (DE)
SCHNEIDER Heiko (DE)
SEMISCH Annetta (DE)
BOYE PETERSEN Annika (DK)
DE RIVAS Ana (ES)
SÁNCHEZ José María (ES)
HYVÄRINEN Tuija (FI)

RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
COLLIN Elodie (FR)
REY Marion (FR)
MCCANN Andrew (IE)
DEKOVI Edlira (IT)
ANDERSEN Hilde (NO)
FRYDENLUND Jorid (NO)
GAUSTAD Astrid (NO)
MIDTHAUG Hilde Karin (NO)
GÓRECKI Roman (PL)
PETTERSSON Emma (SE)
ČEBAŠEK Petra (SI)
OLHA Roman (SK)
PILIŠIOVÁ Ružena (SK)
Advisors
MANI Orlando (CH)
GEBEL Thomas (DE)
MAUL Katrin (DE)
PEISER Matthias (DE)
STUHLDREIER Fabian (DE)
BELLINGARD Valérie (FR)
CHATZIDIMITRIOU Eleni (FR)
DJAE Tanalou (FR)
GIOVINETTI Maria Christina (IT)
SABAH Ahmed (SE)
ECHA Staff
AIRAKSINEN Antero
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
HYYTINEN Eija-Riitta
PAPADAKI Paschalina
RUGGERI Laura
SPANU Claudia
VASILEVA Katya

Applicants
Afepasa
ARCHE
Christiansen SARL
Micro-Pak
Procter & Gamble
Thor
Stakeholders
VAN BERLO Boris (CEFIC)
Experts: LODINI Sara, LOREZ Christine

WG Human Health

Dermal absorption of rodenticides

Meeting date	18 March 2021
Presenters	DE Biocides for Europe / Cefic
Previous discussions	Closed session at WG-IV-2020
S-CIRCABC WG folder	https://webgate.ec.europa.eu/s-circabc/w/browse/be0bae35-0c88-4176-a591-4474fb2bf41e

This discussion table concerns the following documents:

Discussion point	Document number	Document name	Provided by
1	WGI2021_TOX_9-4a	*Dermal absorption values for anticoagulant rodenticides*	DE/BfR
	WGI2021_TOX_9-4a1	*BfR replies to the comments from the MS and ECHA*	DE/BfR
2	WGI2021_TOX_9-4b	*Dermal absorption values for anticoagulant rodenticides - Proposal for an alternative approach for the occupational setting*	DE/BAuA
	WGI2021_TOX_9-4b1	*Summary of the e-consultation and conclusion (including RCOM)*	DE/BAuA
3	WGI2021_TOX_9-4c	*Justification for not applying the pro-rata approach, included in the EFSA guidance on dermal absorption, to rodenticides for the extrapolation from test concentrations of 50-75/790 ppm active substance to 10-30 ppm active substance*	Biocides for Europe/Cefic
	WGI2021_TOX_9-4c1	*Industry feedback on "Input received from MSCAs and SECR" on the Biocides For Europe paper regarding "Justification for not applying the pro-rata approach, included in the EFSA guidance on dermal absorption, to rodenticides for the extrapolation from test concentrations of 50-75/790 ppm active substance to 10-30 ppm active substance" for BPC HH WG-I-2021*	Biocides for Europe/Cefic
	WGI2021_TOX_9-4c2	*Comments from MSCAs and SECR on the Cefic document*	Comments compiled by SECR

SECR note: A relatively large number of comments were submitted in commenting the three documents. SECR considers that most of them are sufficiently addressed in the responses by DE, and these are not specifically included in the points below. However, any of the comments made can still be raised in the context of the appropriate document.

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Discussion table – Dermal absorption of rodenticides			
a) No	**b) Issue and background** Reference in RCOM	**c) WG discussion** Ad hoc follow-up where relevant	**d) Conclusions and action points**
1.	<u>Harmonising dermal absorption assessments</u> Documents: WGI2021_TOX_9-4a (BfR proposal), WGI2021_TOX_9-4a1 (RCOM) The members, SECR and Cefic in general supported the document. Some specific comments are noted in the Background below. CH noted that the EFSA dermal absorption guidance may not really represent the particular case of the first and second generation anticoagulant rodenticides (FGAR, SGAR) bait products, as there were only 6 bait products in the assessed database of over 400 PPP formulations. DE agreed that the EFSA guidance should be applied cautiously for all biocides, in particular rodenticides, and proposed to use it in general, unless deviation can be scientifically justified. CH and IE also noted that for a harmonised read-across approach, well-defined justification criteria should be developed. DE agreed on the need for robust justification criteria, but noted that without further data it is hardly possible to develop such criteria (as demonstrated by the example of a non-justified read-across between difenacoum and brodifacoum where the physico-chemico properties cannot be considered sufficiently similar). **To be discussed:** - Whether the members in general agree to cautiously apply the EFSA guidance also to AVK rodenticides, unless deviations can be scientifically justified - Whether the members agree that it is currently not possible to develop detailed read-across justification	An ASO observer asked on a general level on the applicability of the EFSA dermal absorption guidance for AVK rodenticides. DE and SECR noted that in principle the EFSA guidance is agreed to be used for biocides and it should be followed in deriving dermal absorption values, while deviations could be justified regarding similarity, read across and pro-rata. The members agreed that the EFSA guidance should be applied with caution to the AVK rodenticides, noting that the methodology for study conduct in EFSA guidance has to be applied while deviations on other aspects may be acceptable when scientifically justified. An ASO observer noted that it may be possible to have extrapolations other than pro rata, especially for lipophilic substances, where adding the whole skin depot is questionable, as requested by the guidance, and noting the guidance requirement to reach 95% recovery. Therefore, more specific discussion may be needed for particular groups of compounds, e.g. AVK. DE noted that regarding recovery, normalisation is considered in the new proposal. The members agreed that although the read-across principles could be applied, there is insufficient information to develop guidance or detailed justification criteria for read across. It was noted that information on phys-chem properties and good experimental data including the study shortcomings are important in concluding on read-across. In this regard, DE was asked to further elaborate chapter 3 in the BfR proposal, by adding the above-mentioned considerations. In conclusion, the members agreed on the BfR proposal, noting that the revised chapter 3 will be provided for e-	Point closed **Conclusion:** The WG agreed on the document. The members agreed to cautiously apply the EFSA guidance also to AVK rodenticides, unless deviations can be scientifically justified. The members agreed that it is currently not possible to develop detailed read-across justification criteria, but proposals on criteria would be welcome. **Action point:** DE will include in chapter 3 (read-across) the information referred to in the discussion. Following an e-consultation, the revised document will be considered as agreed, or will be discussed at the WG if critical comments are received.

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	criteria - Whether any changes are needed in the document - Whether the document is agreed	consultation to members and ASO observers after the meeting.	
	Background CH: In general, we agree that the guidance 2017 should be used for the assessment of the DA of AVK products. However, we think it important to keep in mind, that the database used for the EFSA DA guidance 2017 contains over 400 different formulation types of PPP, of which only 6 were bait products (ready for use; paste, wax bloc, pasta bait).Therefore, we are not convinced that the guidance really represents the particular case of the SGAR and FGAR bait products and think it to be acceptable to deviate from the EFSA guidance, in this case. **DE** (BfR): We agree that the EFSA Guidance has been predominantly developed for the assessment of plant protection products and not for rodenticides. For those points in the guidance, which are related to the formulation database, we agree that they needs to be handled cautiously for rodenticides. This is – in our point of view - sufficiently addressed in the document [e.g. for read-across between different baits, pro-rata approach, see also your point (5)]. However, this is a general problem for all biocidal products and not limited to rodenticides. As it was decided by all MS to use this Guidance for biocidal products, we propose to use it in general, unless deviation can be scientifically justified. CH: We also agree to only allow read-across between SGARs or between FGARs if sufficiently justified. However, we think it important in order to have a harmonized way forward that the justification criteria should be defined more in detail. IE: Agree to allow read-across between AVKs if sufficiently justified. However, we think it's important that the justification criteria are better defined. **DE** (BfR) to CH and IE: We agree that more robust justification criteria for active substance read-across should be available. However, to define such criteria without further data is hardly possible. We were only able to point out in our presentation on BPC-WG-IV-2020 that a read-across between difenacoum and brodifacoum is not justified. As a reaction on your comment, we added this example to this section. This example does not define more specific criteria, but it describes a situation where the physico-chemico properties cannot be considered sufficiently similar.		
2.	<u>The alternative approach</u> Documents: WGI2021_TOX_9-4b (BAuA proposal), WGI2021_TOX_9-4b1 (RCOM) The members, SECR and Cefic in general supported the approach. Some specific comments are noted in the Background below. IE asks generally whether sufficient conservatism is ensured. DE does not expect any systematic underestimation for lipophilic substances. The only change request was made by SECR, supporting the	The members supported the proposed alternative approach and its tiered application (when risk is identified, the alternative approach could be applied) in a flexible manner and with relevant scrutiny on the first cases. Different views were expressed on whether to use the total area of the two palms (410 cm^2) or of the fingers only (205 cm^2) in the risk assessment. An ASO observer noted that palms are the least permeable skin area of the human body, while usually the more permeable abdominal skin is used in dermal absorption studies. One member also suggested to take into account the type of the formulation, as the value 410	Point closed **Conclusion:** The WG agreed to start using the alternative approach as a Tier 2 approach in a flexible manner. The total area of two palms (410 cm^2) will be used as the exposed skin area of the worker.

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	value 205 cm^2 instead of 410 cm^2 to be used as the total area of exposed skin (fingers only), representing 1/4 of the default value for palms and backs of the hands (820 cm^2) in HEAdhoc 14. DE prefers not to change the value but is open to discuss. Proposed approach SECR proposal: If agreed by the WG, we propose to start using the alternative approach in a flexible manner, as a refinement when the traditional methodology indicates a risk or is safe only with gloves. Sufficient scrutiny (peer review) should be ensured for the first cases coming for assessment, and the relevant MSCA (eCA, RefMS) would be expected to be proactive in this respect. The Human Health WG can be used as the discussion forum if considered appropriate. **To be discussed:** - Whether the members agree to start using the alternative approach in a flexible manner - Whether the members agree to use the total area of two palms (410 cm^2) as the exposed skin area of the worker - Whether any changes are needed in the document - Whether the document is agreed	cm^2 could be used for grain baits and 205 cm^2 for block baits. A discussion took place on the need to clarify if the approach should be applied to trained and not trained professional users, due to differences among MSs in this regard. DE clarified that the alternative approach is focused on trained professionals as worst case, considering daily 24 h exposure that would not be relevant for non-trained professionals or non-professional users. DE also clarified that if used for professionals that are not exposed on a daily basis, the assessment will be more conservative than for those exposed daily. Thus, there is no need to distinguish between different groups of workers. An observer noted that by applying the alternative approach for shorter exposure duration (e.g. 8 h only), a more realistic assessment could be achieved. This proposal was not further discussed. The members agreed that further development of this approach could be done at a later stage, with potential adaptations for different user classes. In conclusion, in the absence of experience with the new approach and considering that the conservatism is not proven, the members supported 410 cm^2 to be used in the assessment as the exposed skin area of the worker while 205 cm^2 might be used as further refinement, taking into account also the type of the formulation.	
	Background IE: The conservatism of including the skin and stratum corneum in the EFSA 2017 method is likely very substantial and amply covers the limitations of the testing methodology. The discussion on limitations in your proposal is very informative. However we wonder is the approach sufficiently conservative to cover the limitations of the testing methodology (including difficulties with lipophilicity and the very low concentrations in rodenticide products). **DE** (BAuA): Due to the conservative elements of the alternative approach mentioned at the beginning of the section "Discussion & limitations", the results of the discussed paper by Lehman et al. (2011) and the use of appropriate receptor fluids in the studies evaluated by the BfR, a systematic underestimation of the dermal absorption of lipophilic substances is not to be expected. NL: We would like to have a general discussion on when/how this alternative approach will be used. E.g. for professional use if the EFSA method is save with		

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	gloves, do we also calculate the alternative method? **DE** (BAuA): This is something we should agree if the MS decide that we use the alternative approach for professional use. An agreement when to use the alternative approach is necessary to avoid discrepancy in our decisions. In line with the hierarchy of protective measures set out in the Council Directive 98/24/EC we would prefer to apply the alternative approach in case the EFSA method would only be save with gloves. Cefic: The BAuA and BfR documents refer to professional use only. PT 14 products are also intended for general public, and the dermal absorption topic affects all categories of users. Why are only professional users mentioned in the documents? **DE** (BfR): The BfR document is for professional and non-professional uses. However, the BAuA approach is not appropriate for non-professional use as it based on the assumption of long-term (daily) exposure. SECR: We should note however that this is a completely new approach that is, as you also mention, conceptually different from the traditional approach. It would therefore be useful to gain some experience on it and to allow some flexibility in the first cases to be assessed. Furthermore, please note that we have not intended to verify any of the calculations. The Human Health WG can be used as a forum for discussing first cases, if considered relevant by the MSCAs. **DE** (BAuA) We share the above-mentioned conceptions regarding the further procedure. SECR: Considering the uses in question and the formulation types, we could support the value 205 cm^2. This would represent the total area of exposed skin of fingers only, and would be 1/4 of the default value in HEAdhoc 14 of 820 cm^2 for palms and backs of the hands). **DE** (BAuA) Regarding the exposed skin area to be used, our exposure experts on site have advised to keep 410 cm^2. Nevertheless, we are of course open for a discussion to adjust this parameter.		
3.	<u>Applicability of pro rata correction</u> Documents: WGI2021_TOX_9-4c (Cefic document), WGI2021_TOX_9-4c1 (Cefic responses), WGI2021_TOX_9-4c2 (comments received) Cefic provided a justification for not using the pro rata correction in assessing dermal absorption of rodenticides. The members in general agreed that pro rata correction should not be applied, and DE prepared a proposal for text to be included in WGI2021_TOX_9-4a. **To be discussed:** - Whether the WG agrees that the pro rata correction should not be applied to AVK rodenticides - Whether the WG agrees on the text proposed below by	The WG took note of the Cefic justification, the room document with EFSA's feedback and the DE justification proposal for not using the pro rata correction in assessing dermal absorption of rodenticides. The members and the ASO observers agreed that pro rata correction should not be used when assessing dermal absorption of AVK rodenticides and supported the proposed justification with a small editorial correction. Further, restructuring of chapter 4 was considered: the members supported keeping in the main text only the justification for not applying pro rata correction, while the arguments in favour of pro rata approach will be included in an annex without further elaboration.	Point closed **Conclusion:** The WG agreed that the pro rata correction should not be applied to AVK rodenticides. The text proposed by DE below will be included in the document "Dermal absorption values for anticoagulant rodenticides", removing however the reference to WG-IV-2020. **Action point:** DE will move to an annex the arguments in favour of the pro

WG Human Health

	DE		rata approach, presented in chapter 4 "Pro rata approach".

Background

CZ, NL and FR in general agreed not to apply the pro rata correction for AVK rodenticides. In addition, CH agreed in the context of commenting the document WGI2021_TOX_9-4a.

DE and SECR asked for clarifications regarding the publication by Aggarwal et al. 2014, as it was already considered in the development of the EFSA guidance on dermal absorption. The guidance refers to deficiencies in the dataset and the industry proposals in Aggarwal study, including some considerations for potential significant "magnitude of underprediction".

DE proposes to include the following justification in the document "Dermal absorption values for anticoagulant rodenticides":

Based on the discussion at the BPC-WGIV-2020 meeting the pro rata approach should not be applied in this specific case (SGAR and chlorophacinone baits with an a.s. concentration below 0.005 %; coumatetralyl baits with an a.s concentration below 0.04 %; warfarin baits with an a.s. concentration below 0.08 %) for the following reasons:

- The performance of dermal absorption studies for rodenticides suffers from some specific methodological problems. Compared to most other biocidal products or to plant protection products the dermal absorption is in general relatively low. For such low values, the variability is in many cases higher than for formulations that are more concentrated. This is enforced by the complex matrix of these formulations. These matrices are optimized to be ingested orally whereas the most plant protection products are designed to wet foliar surfaces of plants. This design is often linked to an improved dermal uptake in humans. In addition, the commercial availability of radiolabeled test compounds is limited. Therefore, they are often replaced by non-labeled test compounds, which are determined with less sensitive analytical methods. The resulting dermal absorption values (taking into account the resulting high variability when derived according to EFSA Guidance) are, therefore, sufficiently conservative for the relevant a.s. concentration range.
- Based on the available studies, no trend is observable supporting or not supporting the applicability of the pro rata approach.
- The differences in concentrations between the single formulations are normally low, in general, not increasing a factor of 2. Due to the high variability in single studies, there is no statistical evidence for the application of the pro rata approach.
- The EFSA Guidance on Dermal Absorption has been mainly developed for the assessment of plant protection products, which are normally liquid concentrates subsequently diluted with water. Normally, the pro rata approach is applied for the derivation of dermal absorption values for higher dilutions of the plant protection product than the highest tested dilution in a corresponding dermal absorption study. The number of rodenticides included in the dataset of the guidance is very low and they are performed normally with only one concentration. They are not diluted before application. Hence, they are not relevant for the justification of the pro rata approach.
- In conclusion, the pro rata approach is considered as not justified in this specific case and in the common active substance concentration range of these biocidal products due to the high variability and uncertainty of dermal absorption values derived from in-vitro studies.