Minutes of the Working Group meeting I in 2020

Analytical Methods and Physico-Chemical Properties

(Meeting date: 24/25 March 2020 – WebEx meeting)

08 June 2020

1. Welcome and apologies

The meeting was a WebEx-meeting. The Chair welcomed the participants of the working group meeting. A representative of CEFIC was present at the meeting as an accredited stakeholder organisation (ASO).

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

2. Administrative 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). No further items were added to the agenda.

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 V 2019

The working group members provided two comments on the draft minutes of WG V 2019:

The modifications were presented and agreed. No further comments were expressed at the meeting. The minutes of the working group meeting V in 2019 were agreed by the working group members.

6. Outcome of e-consultation and discussion

The outcome of e-consultations was presented to the working group members and discussed.

7. Discussion of Union authorisations

7.1. UA for product family containing hydrogen peroxide PT 01, 02, 03, 04 – eCA: LV

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

7.2. UA for product family containing propan-2-ol PT 02 – eCA: NL

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

7.3. UA for product family containing permethrin PT 18 – eCA: BE

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

7.4. UA for product family containing 1R-trans-phenothrin PT18 – eCA: BE

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

8. Discussion of active substances

8.1 Active chlorine generated from sodium chloride by electrolysis Article 75(1)(g) - eCA: SK

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

8.2 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) PT 06 – eCA: FR

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

8.3 Carbon dioxide generated from propane, butane or a mixture of both by combustion PT 19 – eCA: FR

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

8.4 Creosote renewal PT 08 – eCA: PL

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

Annex 1 - List of attendees registered for the meeting

Country	Members of WG
Austria	Zutz Christoph
Belgium	Burmistrova Anastasia
Belgium	Fauconnier Steven
Belgium	Lepage Anne
Belgium	Tordoir Charlotte
Switzerland	Aeschbacher Michael
Germany	Bülter Heinz
Denmark	Jespersen Cindy
Denmark	Erlingsson Natja
Estonia	Ilmarinen Kaja
Greece	Maragkou Niki
Greece	Tzanetou Evangelia
Finland	Vuorensola Katariina
France	Chabanny Loic
France	Six Therese
France	Weber Philippe
France	Gour Annabelle
France	Boitier Caroline
Latvia	Igaune Ieva
The Netherlands	Blaga Cornelia
The Netherlands	Huizing Tjaart-Jan
The Netherlands	Kruidhof Sabine
Norway	Helgerud Trygve
Norway	Stave Sekkenes Marianne
Sweden	Alpe Mia
Sweden	Österwall Christoffer
Slovakia	Mikolaskova Denisa

ECHA staff
Krebs Bernhard (Chair)
Glans Lotta
Matthes Jochen

Company	Agenda item	Observer
Aqualution Systems Ltd	8.1 - active chlorine generated from sodium chloride by electrolysis	Nicholas Meakin
Thor GmbH	8.2 - 5-chloro-2-methyl-2H-isothiazol-3-one (CIT)	Schoester Monika Simonides Michael

Exponent International	8.3 - Carbon dioxide generated from propane, butane or a mixture of both by combustion	Pemberton James
Creosote Council Europe	8.4 - Creosote	Meulepas Ralph Höke Hartmut
Ecolab Germany GmbH	7.1 – UA for product family containing hydrogen peroxide	Geering Christopher Forth Peter
Valtek Associates Inc. Europe	7.2 – UA for product family containing propan-2-ol	Deschenes Pam Eaves Samantha
Aero-Sense	7.4 – UA for product family containing 1R-trans-phenothrin	Vervaecke Dieter

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

WG-I-2020
Final minutes
10 June 2020

Minutes of Efficacy WG-I-2020

31 March, 16, 22, 29 April and 6 May 2020

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 31st Efficacy WG meeting and informed that this meeting is split into several separate parts due to the COVID19 situation.

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

2. Administrative issues

SECR gave brief information on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items. The EFF WG members agreed on the proposed agenda.

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

The Chair invited all members to declare any potential conflict of interest to the agenda items. Boris Van Berlo (CEFIC) declared not to participate in agenda items 7.2 and 7.

5. Minutes

DE and ASOs had sent comments on the EFF WG-V-2019 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 31.03.2020

6.1 Creosote - renewal of approval (eCA PL)

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

6.2 CIT (eCA FR)

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

6.3 Carbon dioxide generated from propane, butane or a mixture of both by combustion (eCA FR)

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

7. Discussion of Union Authorisations – 31.03 and 22.04.2020

7.1 UA for product containing Propan-2-ol (eCA NL)

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

It was mentioned that a general discussion is needed on how the application rate for surface disinfection (volume of product applied per unit of area) should be defined and demonstrated, especially for highly volatile substances. The EFF WG has previously agreed that it needs to be ensured that the surface is wetted completely with the application of the product, and that for wipes passing EN 16615 after the claimed contact time is regarded as acceptable to indicate that sufficient wetting occurred without rewetting/keeping the surface wet. There is, however, no harmonised agreement for other application methods than wipes on whether the surface needs to remain wet for the whole contact time stated, and on whether and how evaporation rates should be taken into account in defining the

minimum volume of product to be applied. It was agreed that the NL will prepare a draft document for discussion at the next WG meeting in June.

7.2 UA for product containing permethrin (eCA BE)

There were seven provisionally closed points. The Chair asked the EFF WG members if any of these points should be reopen. All points remained closed without discussion at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

7.3 UA for product containing 1R-trans phenothrin (eCA BE)

There was one provisionally closed point and it remained closed without discussion at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

7.4 Early WG on UA for product family containing L(+) Lactic Acid

There were three open points raised by the eCA. Please refer to the confidential minutes in the form of the discussion table for more details.

8. Technical and guidance related issues – 16/22/29.04 and 6.05.2020

8.1. Vol. II, Parts B+C – PT19

The EFF WG continued working on PT19 draft guidance. The WG-I-2020 discussion was split into three separate days. Finally, all scheduled chapters were successfully discussed.

Validation of AIC (Arm-in-cage) test

Presentation was given by EBPF/AISE. The main aspects and WG opinions are listed below.

Use of a sleeve – the benefits of using a sleeve in AIC test were presented, e.g. deviations reduction in CPT, more realistic field-like conditions, more comfortable conditions for volunteers. Sleeves were accepted to be used in AIC test, in addition data generated with and without sleeves should be treated equally as long as the agreed landings per min are met.

CPT (complete protection time) – ASOs proposed to revise current definition included into the PT19 draft in order to better reflect the CPT. It was pointed out that the current definition is not a 'new' definition it is just more detailed definition of the EPA guidance. Indeed, this definition is different from the current WHO guidance but this guidance is not considered as very pragmatic especially in relation to AIC test. Therefore the EFF WG members disagreed to change the definition of CPT included in the current draft.

Test species – *Culex* spp. was proposed to be removed from test species used for the general claim against mosquitoes, as it is a less aggressive species in comparison to *Aedes* and *Anopheles* spp. The EFF WG members disagreed because this is the common mosquito in Europe, mostly active at dusk and at night, and as repellents are very species specific there is a need to assure that *Culex* spp. will be repelled.

Landing pressure – some variations in landing pressure were proposed, e.g. to set up a maximum value. Finally, the EFF WG agreed that as a requirement only a minimum of 20 landings per minute is needed.

Label claim – with reference to CPT it was proposed to use the phrase *'up to X hrs'* in the SPC and consequently on the label. The EFF WG members agreed with such proposal.

Room test – new protocol for the room test was presented by ASOs as an alternative for AIC test. The results (landing pressure) obtained in the room test were comparable to AIC test. The EFF WG agreed to include room test into the draft guidance to be

performed alternatively to the AIC test. Detailed description of this test will be sent by ASOs to DE to be included into the draft guidance.

Mosquitoes

Final discussion at WG level took place for this chapter. It was agreed that for topical repellents used on human skin, clothing and treated articles, only the simulated use test should be required for CPT determination. For products intended to be used as topical repellents for human skin the probing or biting per minute value for *Culex* spp. in field test was not agreed upon, it will be done based on some data in cooperation with EBPF/AISE. For this use also Arm-to-cage test was accepted.

The sentence "*Testing for water stability should be performed, especially for products with a claim of residual efficacy"* will be removed from field test paragraph in the section: Products intended to be used as spatial repellents.

It was also agreed that in the section: Attractants without insecticidal active substance (according to PT18) the description of the field test should be less detailed as there is not enough knowledge at this moment how the mosquitoes should be measured. With reference to treated articles mentioned in the draft guidance the decision to keep or remove them from the final version will be taken at a later stage.

Stable flies

A question was raised whether chapters on "Stable flies" and "Flies on grazing cattle and horses" should be merged, since these chapters deal with the same species, but are separated only based on indoor and outdoor uses. Merging is impossible at this step, but the WG agreed that the requirements and criteria shall be harmonized between these two chapters. Also, the potential for transmission of pathogens should be mentioned in the chapter of stable flies.

It was agreed that the applicant should have a possibility of submitting either simulated-use test/semi-field test or field test as the requirements between simulated use and field tests are very similar. It was also agreed that a sentence explaining the critical factors in choosing the animals for testing, i.e. characteristics that might affect the efficacy, such as hair length and colour will be added to avoid mistakes in test design.

For the field test it was agreed to require minimum ten untreated and ten treated animals. Preferably all 20 animals should be tested in the same location, they can be divided in two separate tests: 5 + 5 animals twice in the same location or 5 + 5 animals in two different locations.

The requirements for attractants used in traps were agreed to be adjusted to be in line with "Fruit flies and Scuttle flies" chapter. For field tests, requirement for ≥80% reduction in fly activity was discussed. The term "fly activity" was decided to be left open for applicant to define and justify how the activity was measured.

Fruit flies and Scuttle flies

It was pointed out that the sentence: "*In order to proof the choice of the flies, the distance between food source and trap should be large enough to avoid accidental catching of the flies due to undirected movement*" in simulated-use test for attractants does not define the distance between food source and trap, and leaves room for interpretations. The WG agreed that since there is a wide variety of compounds and products, the guidance should be flexible in relation to the distance between food source and trap, thus the distance used in the test should be reflected on the label of the product.

The traps and control traps were decided to be tested in separate test settings like was agreed previously for mosquitoes chapter.

Different efficacy requirements for professional and non-professional users were discussed. The difference between the requirements in this chapter were justified by

the potential risk of pathogen transmission by scuttle flies in hospitals. The WG agreed to require ≥80% reduction in population for both professional and non-professional uses, in addition an instruction that the product should be used in combination with integrated pest management system or hygiene measures should be added in the SPC.

Flies on grazing cattle and horses

It was agreed that the name of this chapter will be changed to "Flies on cattle, horses and other livestock". As the chapter then includes more host animals more pests were included as well. Also, the housefly (*Musca domestica*) was decided to be included in this chapter, since it is relevant for all livestock. Since the products are often very specific in terms of target organisms and host animal, WG agreed that the general claim against flies is not relevant and thus is not allowed. It was left open for the applicant to choose the relevant test species according to the target organisms and host animal and justify the choice.

Laboratory tests are not advisable for product evaluation, but laboratory colonies of insects can be used in a simulated-use/semi-field test. Either simulated-use test or field test is required.

Regarding the attractiveness of the test animals and the infestation level they need to be established, justified and reported by the applicant. No threshold number was set.

It was agreed that ≥80% repellency in fly activity is required for claimed use period. "Fly activity" should be defined and justified by the applicant.

Textile-attacking insects

With reference to life stages of tested insects a sentence "*If products are exclusively claimed against larvae of moths and/or carpet beetles than the efficacy should be demonstrated for that developmental stage (instead of adults)*" will be added.

It was agreed that it is possible to have a general claim (excluding pheromones). Nevertheless, in case a specific developmental stage, e.g. larvae, adults or species specific claim is made efficacy against this specific stage/species has to be proven. If pheromones are used as an active substance, only the tested species can be claimed.

A sentence "*The composition of the material to be protected should be indicated on the label, to avoid application of products which are not attractive to textile-attacking moths and/or carpet beetles*" will be added.

The efficacy criteria for repellents against textile-attacking insects were agreed respectively: Depending on the claim, damage to test material is relevant. For a claim against adult moths ≥80% repellency is required. If "Protects textile" or "prevents larvae from feeding" is claimed, no damage to the test material can be detected. Also, a sentence explaining the nature of repellents "Make sure there is no infestation in place before the use of repellent. Repellents should be used as preventive measure" will be added.

Stored goods attacking insects and mites

Clarification of defining the product type in case of wood-attacking insects and whether PT8 tests and requirements should apply to PT19 products were discussed. NL clarified that if the wood-attacking beetles are controlled by killing them, the product would either fall under PT8 or PT18. If the wood is protected by a product that repels the beetles or attracts them to a trap, in a way that prevents the insects from reaching the wood, it would be considered a PT19 product. Thus, the PT8 tests and requirements are not applicable to PT19 products.

Information on shelf-life testing will be removed as this is covered in the general chapter.

The name of the chapter was proposed to be changed from "Stored goods-attacking insects and mites" to "Stored goods-infesting insects and mites". Even though

"infesting" is more appropriate and scientific than "attacking", to maintain the consistency the WG agreed to keep the chapter name as it is. The term "infesting" will be included in the introduction of the chapter.

Possibility to have a general claim against stored-goods attacking insects seems to be not possible due to high diversity of the target organisms, thus defining representative test organisms for the whole group is difficult. This point was left open to be discussed again in WG meeting in June. NL will contact EFF experts individually and prepare a proposal.

A general claim for both repellents and attractants should not be made, unless well justified.

A simulated use test is required for non-professional use, in case a robust field test is submitted the simulated-use test can be waived. For professional use only field test is accepted as big warehouses are difficult to simulate.

It was agreed that only ≥ 80% repellency is required. No differentiation between criteria/requirements and uses, the same criteria applies for both professional and non-professional users.

ECHA: Discussion on possible general claim against stored-goods attacking insects initially planned in June was postponed to September.

Ticks

With reference to life stages tested it was agreed that only relevant life stages of each species should be tested. If two different life stages, i.e. nymphs and adults, are tested, the lower CPT should be claimed.

Minimum 12 volunteers should be tested for field test, the results need to be statistically robust. No control group is required due to ethical reasons. Field test is not required and can be submitted only as supportive data.

Criteria for simulated use test of repellents will be slightly rephrased to provide more clarity.

WG agreed that the number of individuals required for field trials for repellents applied on animals should be in line with the requirements for testing of veterinary medicine products.

Worst case testing conditions (characteristics of host animal: hair length/colour, size of the animal, etc.) for different types of products will be added.

The discussed chapters will be revised by the leading MSs.

8.2. Vol. II, Parts B+C – PT11

The draft guidance has been discussed at EFF WGs V-2018, II-2019, and V-2019. In addition to the guidance document a draft for a claims matrix was presented at WG-I-2017, where several claims being in the borderline of different PTs were identified as requiring COM/CA consultation. A position paper regarding scope-related issues has been prepared by Cefic-EBPF, and discussed at 85th CA meeting in September 2019, and 87th CA meeting in February 2020. The discussion will continue at 88th CA meeting in May 2020 (agenda item 8.1). SE promised to send some further information regarding the scope discussion, and encouraged the EFF WG members to liaise with their CA representatives to provide input to the discussion.

TOC/DOC (Total/Dissolved Organic Carbon) concentration in synthetic model water

The realistic concentration of organic carbon in the model water was discussed, and it was agreed to indicate a maximum concentration of 100 mg/L DOC (equal to adding approximately 200 mg/L yeast extract).

Tests against amoeba

Test organism in a simulated-use test against amoeba was discussed. IND explained that *Acanthamoeba* species are known to host *Legionella*, and promote their replication inside the amoeba. Preventing formation of biofilms, which amoeba graze, is a way to control amoeba and *Legionella* populations. *Naegleria fowleri* is a specific problem because of its pathogenicity, and therefore *Naegleria* species have been proposed as test organisms. There could also be an interest for a specific claim against *Naegleria fowleri*, but this strain is very complicated to handle in the laboratory. Furthermore *Naegleria* species are not widespread, whereas *Acanthamoeba* species are common in different cooling systems. In addition, *Acanthamoeba* cysts have been shown to be more resistant to biocides than those of *Naegleria*. The EFF WG agreed to use *Acanthamoeba* species as test organisms in both laboratory and simulated-use tests for a general claim against amoeba.

A question was raised whether cysts should be tested for a general claim against amoeba. It was noted that due to their resistance cysts need much higher application rates than trophozooites, and that the main aim is to control trophozooites, which are able to multiply. The EFF WG agreed that for a general claim against amoeba it is sufficient to test trophozooites, and cysts need to be tested, if claimed. In the SPC trophozooites and cysts can be differentiated in the "Developmental stage" field.

Regarding the required log reduction it was noted that the amoeba levels in the field are estimated to be 100-1000 cells/ml, and simulated-use test should be regarded as the worst-case. It was agreed to require a 3 log reduction in both the laboratory and simulated-use test against amoeba (for a curative treatment).

According to some comments the simulated-use test, as presented in the draft guidance, was considered too demanding compared to tests against other target organisms, and difficult to perform. Therefore, the EFF WG agreed to accept as well:

- a laboratory test and monitoring data; or
- deviations from the simulated use test method cited in the guidance, if clearly described and justified.

Since the methods of detection of amoeba are not well standardised, it was agreed to require two different quantification methods, preferably one based on growth and the other on DNA. The reduction of 3 logs should be obtained with both methods.

Requirement of growth in the untreated controls

It was agreed in WG-V-2019 that for preservative claims, statistically significant growth should be shown in the untreated controls. Since growth is not clearly defined in Vol II Parts B+C guidance it was agreed to require 0.5 log increase with statistical significance to show growth. A need for a general discussion on statistical significance before the finalisation of the guidance was identified. DE offered to gather some information for a discussion of statistical significance.

Test bacterium for preservation of in-use wood treatment solution

It was agreed that for the challenge test a natural inoculum from sawdust, together with *Pseudomonas aeruginosa*, should be used when bacteria are claimed. For fungi, sawdust should be used in combination with the organisms named in Table 2.

PT12 part of the draft guidance is scheduled for a discussion at WG-II-2020, and it was noted that it would be highly beneficial if EBPF could identify expert(s) to participate in the WG discussion.

8.3. Harmonized approach to determine a worst case (or representative) test product for a disinfectant BPF (DE)

DE presented the document revised based on comments received at the EFF WGIV2019 and from the e-consultation in January 2020.

The WG confirmed the conclusion in the revised version that to substantiate the choice of representative worst case product the applicant needs to perform bridging studies (phase 2, step 1 studies). This is also important with reference to determination the effects of co-formulants on efficacy of the product in question. The test conditions should represent the hardest conditions claimed in the application.

Proposed 0.3 log difference between the results from the bridging studies was considered too low. Difference of 0.5 or even 1 log were proposed instead. As there was no clear agreement this point was left open for future discussion.

As proposed in the document the most tolerant strain of each claimed target organism group was agreed to be used for bridging studies. It was also pointed out that sometimes additional information/tests needs to be provided to justify the organism(s) chosen by the applicant. This will be added to the Q&A part (Appendix 2).

IND indicated that if the most tolerant strain, the hardest conditions and the worst case product are used in efficacy testing, it might lead to overdosing for some of the products in the family.

The impact of co-formulants raised some doubts, which were not solved during discussion, e.g. high number of tests needed/applicability of literature data/possible waivers. There is a need to find a compromise between scientific assessment and expected workload. This point was left open for future discussion.

It was agreed that usually no testing for combination effects of co-formulants will be required, since that would increase the number of tests needed significantly.

This document will be revised by DE and circulated for comments. Next discussion is planned at the EFF WG-III-2020.

8.4. P2S1 test requirements for PT5 disinfectants (FI) – closed session

Please refer to the confidential minutes: *WGI2020_EFF_minutes_draft_confidential.*

8.5. Virucidal activity – PT2 (NL)

The revised EN 14476 and EN 16777 allow differentiated virucidal claims for PT2 surface disinfection. The EFF WG discussed whether limited spectrum virucidal claim and claim against enveloped viruses should be allowed in PT2. The working document was prepared by NL in cooperation with DE and FR.

The WG agreed that:

- For PT2 surface disinfectants used in healthcare areas, in addition to the currently accepted full virucidal claim, also the limited spectrum virucidal claim and the claim against enveloped viruses are allowed;
- For PT2 surface disinfectants used in non-healthcare areas by professional users, in addition to the currently accepted full virucidal claim, also the limited spectrum virucidal claim and the claim against enveloped viruses are allowed;
- For PT2 surface disinfectants used in non-healthcare areas by general public only a full virucidal claim and claim against enveloped viruses are allowed.

The agreement in the last bullet point that a claim against enveloped viruses is allowed also for PT2 surface disinfection in non-healthcare areas for non-professional users was made due to the current situation with coronavirus.

NL will provide a proposal in TAB format to be agreed at EFF WG-II-2020.

9. AOB

9.1. Other information & lessons learned

All details are in the working document: *WGI2020_EFF_9-1_Other info&lessons learned* available in S-CIRCABC.

TAB proposal presented by FR: Efficacy of an insecticide for use in stables.

WG agreed on TAB entry as follows:

Can sticky traps be used as an appropriate and reliable method to estimate and monitor population of flies in stables?

Use of sticky traps is an appropriate and reliable method to monitor population of flies in stables when generating field data. The use of another indirect measure like the Danish Pest Infestation Laboratory (DPIL) fly index or spot cards is acceptable as well.

What are the appropriate efficacy criteria for field trials of an insecticide to be used against flies in stables?

In the field trials, the efficacy criteria (reduction of the population) should be ≥80%, because of short generation times and possible resistance development. Deviations might be accepted in well justified cases.

SARS-CoV-2 – current situation - approaches of MSs

ECHA has published a webpage on Covid-19 to share all relevant information concerning disinfectants in the EU. Information can also be found from the WHO and ECDC sites.

DE presented a room document: Article 55(1) - hygienic hand disinfection.

Due to the coronavirus outbreak, there might be a shortage of alcohol-based disinfectants. To counteract this, the DE CA has permitted formulations for hand disinfection in accordance with Article 55 of the BPR. DE pointed to a publication (Suchomel et al. 2012, Am. J. Inf. Control 40:328) in which formulations containing humectant (glycerol) together with 80% (v/v) and 80% (w/w) ethanol as well as 75% (v/v) into 75% (w/w) propan-2-ol were compared with respect to the bactericidal efficacy. It turned out that only (w/w) concentrations achieve sufficient bactericidal efficacy within 30s, qualifying them particularily for hand disinfection in the medical area.

It was underlined that it is recommended to advice general public that handwashing with soap and warm water is sufficient against coronavirus, and proposed to have this information also on ECHA webpage.

ECHA consulted the EFF WG members on any further knowledge and experience on active substances against enveloped viruses. With reference to determining minimum concentration for other active substances than those already recommended by WHO or ECDC, the WG members indicated that it is not straightforward, because the formulation and the intended use may profoundly influence efficacy. It was also pointed out that many substances are not as easy to handle as alcohols, e.g. peracetic acid (PAA) is efficacious against viruses, but is unstable and not easy to handle even by professionals. The MSCAs are mainly following the WHO recommendations for hand disinfection, and recommendations for surface disinfection are under development. Hydrogen peroxide, sodium hypochlorite and sodium dichloroisocyanurate were mentioned as substances considered for surface disinfection by some MSs, based on national authorisations and open literature data. MSCAs offered to share any relevant links and information with ECHA.

A question was raised whether the high demand of disinfectants has or will lead to shortage of alcohols. The general information was that shortage of ethanol is not expected (might be from reference sources – Art. 95 suppliers), whereas for propan-2-ol shortages are possible. Current problem are potential shortages of packaging materials (e.g. certain sizes of bottles, trigger dispensers, printing inks).

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
GIATROPOULOS Athanasios (EL)
JANSEN Irina – alternate (DE)
MAXIMILIEN Yann - alternate (FR)
POULIS Joan (NL)
ZUTZ Christoph (AT)
DUH Darja (SI)
Flexible members
BURMISTROVA Anastasia (BE)
BLODÖRN Krister (SE)
BURMISTROVA Anastasia (BE)
CLEYTON JØRGENSEN Charlotte (DK)
DOLEŽELOVÁ Katsiaryna (CZ)
FRANK Ulrike (SE)
KRÜGER Martin (DE)
LEPAGE Anne (BE)
MALMGREN Birgitta (SE)
MEZULE Linda (LV
McGEE Conor (IE)
NIEMINEN Timo (FI)
PECINKOVA Martina (CZ)
PEELMAN Natania (BE)
RONCI Maria Beatrice
ROSSIER Nadine (CH)
RYDMAN Elina (FI)
SCHOEP Piet (NL)
WARMERDAM Sonja (NL)
WIGGERS Hanneke (NL)
ÅSLING Bengt (SE)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
RAULIO Mari
SCHAKIR Yasmin
Applicants
Aero-Sense
Creosote Council Europe
Thor GmbH
Veltek Associates Inc. Europe
Thor GmbH
Spectra Consult GmbH
Advisors
TORDOIR Charlotte (BE)
KROOS Garnet Marlen (DE)
TRAUER-KIZILELMA Ute (DE)
Stakeholders
VAN BERLO Boris (EBPF)
ASHWORTH David (expert)
THEELEN Meredith (expert)
VAN-SLOUN Petra (expert)
MORENO Mara (expert)
GRUSON Bernard (expert)
MORENO Mara (expert)
GRUSON Bernard (expert)

Environment WG-I-2020

Final minutes

15 June 2020

Minutes of Environment WG-I-2020

1-2 and 22 April 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 31 participants present, of which 5 (1-2 April) were core members, thirteen flexible members, two rapporteurs and one adviser. One representatives from accredited stakeholder organisation was 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

SECR gave a brief presentation on administrative issues.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. The agenda was agreed.

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

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None was declared. The chair declared an interest in one of the cases which however were not considered as conflict of interest.

5. Agreement of the draft minutes from WG-V-2019

The minutes were agreed without further discussion.

6. Discussion on active substances

6.1 Creosote – renewal of approval (PL) PT 08

Nine points were discussed in relation to the substance and they were all closed during the meeting. One discussion item was related to the socio economic analysis.
SECR noted that a Public Consultation will be conducted to collect input from all MS in relation to Art 5(2). All MS are expected to provide feedback regarding their national conditions.
A new scenario was agreed for biocides used in vineyard and orchards which will be added in the TAB.

Actions:

- **SECR** to include the vineyard scenario in the TAB.

6.2 CIT (FR)

Eleven points were discussed for this case. One of the points was related to ED properties for non-target organisms to which the WG agreed that no conclusion can be drawn with the information available.
Another item was related to the refinement of the scenario for outdoor treatments.

Actions:
- The applicant will provide a testing proposal based on the principles of the ED guidance and discuss it with the eCA.
- SECR to forward agreed item to the AHEE.
- SECR to take up the discussion of further refinement options for the separate sewage system at the AHEE again.

6.3 Carbon dioxide generated from propane, butane or a mixture of both by combustion (FR) PT 19

There were only two points for discussion, related to classification. One of the points was related to the assessment of precursors and was provided only for information as update was provided following the discussion at TOX WG-I-2020 with respect to how to deal with precursors, which are commodity chemicals.

The second point was related to ED assessment for non-target organisms were the assessment was waived by the eCA.

Actions:
- No actions were identified.

6.4 Harmonised list of endpoints for Pyrethroid metabolites

This agenda item was followed up by written procedure. The WG was consulted via a written consultation for two remaining points. The WG found agreement to the points and therefore could be closed.

Actions:
- No actions were identified

6.5 Active chlorine generated from sodium chloride by electrolysis – ED assessment (SK)

Points 6.5 and 6.6 were discussed together. Two points remained open for discussion at the WG and there was one provisionally closed point. The first point was related to the assessment of ED properties of the substance.
The other open point was related to the presence of one impurity and the need for an ED assessment of that impurity. The WG agreed that impurities of the active substance need to be assessed for ED properties for non-target organisms at the active substance approval stage.

Actions:
- SECR will clarify the next steps with the Commission before proceeding. SECR will contact EFSA to understand how they deal with impurities in cases like this.

6.6 Active chlorine released from hypochlorous acid – ED assessment (SK)

See summary in point 6.5.

6.7 Diamine – ED assessment

The discussion focused on the assessment of ED properties for non-target organisms.
There was one point provisionally closed referring to the fact that several experts requested to present the ED assessment according to the ECHA/EFSA guidance.

Actions:
- No actions were identified

6.8 Azamethiphos – ED assessment

The points for discussion at the WG were related to the assessment of ED properties for non-target organisms. In order to further continue with the assessment the eCA will prepare a testing strategy that will be shared with the WG members through an Ad-hoc follow up.

Actions:
- The eCA will prepare a testing strategy that will be shared with the WG members through an Ad-hoc follow up.
-

7. Discussion of Union Authorisation cases

7.1 UA for product family containing Permethrin - PT 18 (BE)

Seven points were discussed regarding the emission scenarios used, the exposure and risk assessment. All points were closed and the case can proceed to the BPC.

Actions:
No actions were defined.

7.2 UA for product family containing 1R-trans phenothrin - PT 18 (BE)

Two points were discussed, the first relates to the value of PNECsediment, which was not correctly calculated in the CAR of the active substance. The correct PNECsediment value, now confirmed by the ENV WG, is 0.0129 mg/kg wwt. To be noted that this value includes already the assessment factor of 10, which should be applied according to Vol. IV Part B+C to substances with a log Pow higher than five, when using the EPM to derive the PNECsediment from the aquatic PNEC.

The second point concerned the aircraft volume for the emission estimation and a proposal to introduce in the emission scenario the calculation of the "quantity of biocidal product applied in average long haul aircraft".

A third point had been agreed and closed prior to the meeting (action agreed reflected below).

Actions:

- **SECR** to follow up on the correction of PNECsediment in the CAR of the active substance.
- **SECR** to include in the TAB the conclusion that the input parameter "quantity of biocidal product applied in average long haul aircraft" is to be replaced by "aircraft volume" and "application rate" and in the calculation quantity of b.p = aircraft volume x application rate.
- **eCA BE** to update the PAR with the calculation of the concentration of metabolites in groundwater.

7.3 Early WG: UA for single product containing chlorine - PT 02 (BE)

In the frame of this early WG discussion three points related to new scenarios proposed case-specific in PT 2 were discussed and clarified. The eCA will amend the scenarios as

agreed and include them in the PAR. The revised scenarios will be commented by MS in the frame of the PAR commenting period.

Actions:
- **SECR** to prepare a note in the TAB to harmonise the use of dilution factors.
- In general, the urgent need was noted to further define how treatment in on-site STPs should be reflected in calculations. **SECR** to contact **RIVM** to check the status of the related AHEE item.

7.4 UA for product family containing propan-2-ol - PT 02 (NL)

There were no open points identified and the item was closed without further discussions at the WG Meeting.

Actions:
No actions were identified.

7.5 Environmental exposure assessment of products with lime – proposal for the general procedure and new scenarios (DE)

Fourteen questions regarding harmonisation of the exposure assessment of product with lime were discussed, comparing an assessment provided by one applicant with the approach provided in the assessment report (e.g. considering only a single application to grassland) as well as with cases dealt with by other national authorities.

Actions:
- **DE** will propose an approach to consider litter left-overs and a fraction to slurry in a written procedure to receive comments on the new proposal by the MS (BE, NL, ECHA).
- **SECR** to consider whether a new litter scenarios as well as for disinfection of surfaced/unsurfaced outdoor areas should be added to the TAB.

7.6 Chlorate impurity in products based on sodium/calcium hypochlorite (FR)

The questions raised were related to several on-going Union Authorisations currently under assessment. Questions referred to the strategy to follow for the environmental assessment specifically.

Chlorate is a by-product of the manufacturing process and can be formed during storage. It is also a disinfection by-product (DBP). Chlorate is considered as a relevant metabolite in drinking water. The discussion concerned only chlorate as an impurity (i.e., formed only during the storage) of products containing sodium/calcium hypochlorite. Generation of chlorate as a DBP was not considered under this discussion.

1. *Do all MSs agree to use the maximal active chlorine concentration for the environmental risk assessment? (i.e. the initial chlorine concentration before storage), except for ground water (GW) – as ground water assessment is discussed separately (Q2).*

   Conclusion: The WG agreed that chlorate can be assessed qualitatively for all the environmental compartments except groundwater.

2. *Do all MSs agree to conduct a chlorate assessment in groundwater?*

Conclusion: The WG agreed that chlorate can be assessed qualitatively for groundwater.

3. *Do all MSs agree to conduct a chlorate assessment for surface water intended for the abstraction of drinking water? If yes, is this assessment specific to chlorate (because for the moment this assessment is not conducted for the other active substances)?*

   Conclusion: The WG agreed that chlorate can be assessed qualitatively for the assessment of abstraction of drinking water from surface water.

In the discussion a remark was made, that the chlorate drinking water limit of 700 µg/L as mentioned in the document, shall be checked as it might be under revision (in the Drinking Water Directive).

Actions:

- **FR** to cross check the chlorate drinking water limit in the revision of the Drinking Water Directive).

  Post meeting note by FR: This value is under revision to 250 µg/L but only for systems not treated by chlorination. For system treated by chlorination, the limit remains at 700 µg/L.

- **SECR/FR** to receive from applicant/ DBP consortium the RA document on which the Endpoints for chlorate were proposed and distribute to the MSCAs.

7.7 Harmonisation of assessing product authorisations – Follow up WebEx meeting of 3rd April 2020 (ECHA SECR)

Since no guidance is available, applicants submit many different approaches to address disinfection by-products (DBP). In order to harmonise the approaches specific for active chlorine released from sodium/calcium hypochlorite and to discuss how to proceed with the general approach to assess DBP ECHA held a WebEx meeting with interested MSCAs on 3rd April 2020. Several conclusions were drawn at the kick-off meeting, which were brought to the ENV WG for official confirmation.

Conclusions confirmed by the ENV WG:

Harmonisation of the approach for assessing the ongoing active chlorine released from sodium/calcium hypochlorite related product authorisations

Disinfectant-by-product assessment – Conclusion:

It was agreed that for the time being the information provided by the applicants in their dossiers on DBPs of all ongoing authorisation applications should be only summarized and no conclusion should be drawn referring to the current lack of guidance. In fact, all the participants agreed that the current 'guidance' covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.

Relevance of performing a quantitative risk assessment - for active chlorine released from sodium/calcium hypochlorite – Conclusion:

It was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively.

Applicability of this discussion to other active chlorine substances (for example "Active chlorine released from chlorine" but also other active chlorine releasers or active chlorine generated in-situ) – Conclusion:

The above agreed approaches should be applied to all chlorine substances.

Actions:
No actions were identified.

8. Technical and guidance related issues

8.1 Overview on guidance (ECHA SECR)

Item was postponed to the next meeting

8.2 Open TAB entries after TAB v2.1 commenting (ECHA SECR)

Item was postponed to the next meeting

8.3 PT 3 - Disinfection of animal housings – proposal for an assessment approach for the disinfection of calf igloos (DE)

A new scenario for disinfection of animal housings was proposed by DE, to specifically cover the disinfection of calf igloos. An initial proposal by DE had been commented by the other ENV WG and AHEE WG members via an e-consultation and DE reflected the comments in a revised version which was discussed at this meeting. As resulted from the e-consultation that emissions to soil would need to be considered, the following aspects were now discussed and agreed upon: fraction of the emission directly released to soil, soil depth and area exposed.

Actions:
- **DE** to reflect the conclusions of the discussion in a revised scenario document to be included in the TAB.
- **SECR** to include the new scenario in the TAB.

8.4 Revising the WG recommendation on in situ generated substances

A summary of the planned revisions and the suggested way of working was presented at the WG meeting for information.

8.5 Reference values for the groundwater assessment of SoCs (DE)

DE presented a document which had gone previously through an e-consultation. The document aimed to agree on a harmonised reference value for the groundwater assessment of SoC. DE proposed the default reference values of 0.1 µg/L (single substance) and 0.5 µg/L (total of all relevant substances) as a pragmatic approach for the groundwater assessment of SoCs and for the decision making on biocidal product authorisation. Exceptions are (i) inorganic substances which have explicit groundwater reference values according to Directive 98/83/EC (Part B, chemical parameters) and (ii) substance with known toxicological values below 0.1 µg/L.

The WG agreed with the proposal made by DE. The WG reflected on the fact that discussion still ongoing in relation to inorganic substances and the proposal would need to be adapted accordingly.

Actions:
- **SECR** will discuss with **DE** on the way forward for the proposal (e.g. BPC or CA

consultation)

8.6 PT 21 - Scenario for inland commercial vessels and refinement of the leaching rate (NL)

NL presented two documents which had gone previously through an e-consultation.

One document aimed at agreeing on new emission scenarios for antifouling paint on commercial ships on inland waters. Because there was only little response in the e-consultation it was noted not possible to draw conclusions on the acceptance of the scenario. FI, SE and NO welcomed the availability of the scenario but while they have a national ban on the use of antifoulings in freshwater, the scenario is not applicable.

It was agreed that NL will share and discuss the MAMPEC calculation with DE and other interested MS, and check / solve potential issues. Then NL will proceed with using the scenario. For a formal position as a harmonised ESD, a follow up would be needed.

The second document sought support from the MS for the evaluation of supporting data submitted by an applicant to allow refinement of the calculated leaching rates by using a correction factor (CF) of 2.9 (in accordance with the product authorisation manual for PT21 products (ECHA, 2017)). The ENV WG agreed that the data as submitted by the applicant, do not justify the wider applicability of the CF of 2.9 to other copper products, zinc products or salinity ranges. MS showed a lot of interest in the subject of leaching rate refinements and a need for technical discussion/workshop was identified.

Actions:

- ECHA to organize a webinar for the Chalmers presentation.

9. AOB

9.1 Other information & lessons learned (SECR)

ECHA presented several topics:

- With regards to next WG meetings ECHA announced that provisional dates for the next meeting is 11-12 June and the meeting will take place as virtual meeting. Still to be confirmed there may be a EUSES Workshop (12 of June) depending on the number of items scheduled for the WG. WG meeting III for Environment is provisionally scheduled for 16-18 September 2020. AHEE-5 is provisionally scheduled for 15-16 September but still to be confirmed
- ECHA provided an update on the status and planning of the guidance on pollinators. ECHA invited members especially from southern European countries to participate in the Expert Group drafting the guidance to achieve a better geographical balance of the experts. ES confirmed that they would check if they can contribute.
- ECHA provided an update on the status and planning of the Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water. ECHA highlighted the people in charge

9.2 Update on EUSES (SECR)

Item was postponed to the next meeting.

9.3 NL calculation sheets: outcome e-consultation and next steps (SECR)

SECR provided updates on the topic under 9.1. The NL agreed to address the comments received on their spreadsheets in the coming weeks in view of a future publication on the ECHA website.

Appendices:

Appendix 1: List of participants

Core members:

- (DE) Daniel **FREIN** (on 1-2/4)
- (DE) Sascha **SETZER** – alternate member (on 22/4)
- (FR) Stéphanie **ALEXANDRE** (rapporteur)
- (IE) Helena **JOYCE** (on 22/4)
- (NL) Barry **MUIJS** (rapporteur)
- (SI) Petra **MURI**

Flexible members:

- Altmann Dominik (AT)
- Kantner Christian (AT) (on 1-2/4)
- Kührer Lukas (AT)
- Brandt Charlotte (BE) (on 1-2/4)
- Heulens Bart (BE)
- Jarrety Helene (BE) (on 22/4)
- Leroy Celine (BE) (on 22/4)
- Gyalpo Tenzing (CH)
- Kehrer Anja (DE)
- Loskyll Julia (DE)
- Schwanemann Torsten (DE)
- Wennermark Henrik (DK)
- De La Flor Tejero Ignacio (ES) (on 1-2/4)
- Martin Vallejo Myriam (ES) (on 1-2/4)
- Ruiz Lopez Elena Fuensanta (ES)
- Koivisto Sanna (FI) (on 1-2/4)
- Pasanen Jaana (FI)
- Penttinen Sari (FI)
- Straczek Anne (FR)
- De Magistris Isabella (IT)
- Smit Els (NL) (on 22/4)
- Haraldsen Terje (NO)
- Randall Marit Espevik (NO)
- Podlaska Agnieszka (PL)
- Boqvist Pernilla (SE) (on 1-2/4)
- Hahlbeck Edda (SE) (on 1-2/4)
- Konovalenko Lena (SE) (on 22/4)
- Persson Johan (SE) (on 1-2/4)
- Magner Jörgen (SE) (on 22/4)

Rapporteurs (on 1-2/4) **:**

- Lefebvre Frederic (BE)
- Lepage Anne (BE)
- Lorenzetti Stefano (IT)
- Rzodeczko Helena (PL)
- Oliveira Ana Bárbara (PT)
- Mikolaskova Denisa (SK)

Member's advisors:

- Tordoir Charlotte (BE) (on 1-2/4)
- Johannessen Jesper (DK) (on 1-2/4)
- Hänninen Oskari (FI)
- Boitier Caroline (FR) (on 1-2/4)
- Gour Annabelle (FR) (on 1-2/4)
- Convert Yannice (FR) (on 22/4)
- Verstraet Séléné (FR) (Rapporteur - on 1-2/4)
- van der Ploeg Merel (NL) (on 1-2/4)
- Blesak Karol (SK) (on 1-2/4)
- Säll Liselott (SE) (on 22/4)

ASOs:

- Garmendia Irantzu (CEFIC representative) – all agenda items except closed ones (on 22/4)
- Gryspeirt Celia (IMA Europe) (on 22/4)

Human Health WG-I-2020

Final minutes

9 June 2020

Minutes of Human Health WG-I-2020

24-26 March 2020

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 44 members registered, of which 9 were (alternate) core members. Three stakeholder representatives were registered. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR reminded the participants of the WebEx instructions, noting in particular that all persons attending the meeting need to be registered and no other persons may follow the meeting.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The Chair informed the members that item 8.1 *Update on guidance development* has been removed from the agenda. The agenda was agreed without additional 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-V-2019

The minutes were agreed without changes.

6. Discussion of active substances

6.1 Creosote – renewal of approval PT 8 (eCA PL)

The WG agreed that it was not possible to conclude on the ED properties for human health and that information on genotoxicity was not sufficient. The WG agreed that revision of the reference values, in light of the current methodology, would be necessary. The WG discussed uses not included in the first approval, "treated tree support posts (fruit, vineyards)" and "equestrian fences", and concluded that the assessment should be performed and peer reviewed.

6.2 CIT PT 6 (eCA FR)

The WG agreed that CIT does not meet the criteria for endocrine disruption with regard to human health. The WG agreed for consistency with other isothiazolinones that systemic risk assessment should accompany the local risk assessment.

6.3 Carbon dioxide generated from propane, butane or a mixture of both by combustion

PT 19 (eCA FR)

The WG agreed that carbon dioxide does not meet the criteria for endocrine disruption with regard to human health and that no assessment is needed for the precursors. A reference value for the general population was agreed in addition to the reference values set earlier for the active substance in already approved PTs.

6.4 Active chlorine generated from sodium chloride by electrolysis – ED assessment

PT 1, 2, 3, 4, 5 (eCA SK)

The WG considered that based on the available information it is not possible to conclude on the ED properties of this active substance in respect to human health.

6.5 Active chlorine released from hypochlorous acid - ED assessment

PT 1, 2, 3, 4, 5 (eCA SK)

The WG considered that based on the available information it is not possible to conclude on the ED properties of this active substance in respect to human health.

6.6 Azamethiphos – ED assessment PT 18 (eCA IT)

The WG considered the available data sufficient to conclude that azamethiphos does not meet the criteria for endocrine disruption with regard to human health.

6.7 Diamine PT 2, 3, 4, 6, 8, 11, 12, 13 (eCA PT)

The WG considered the available information not sufficient to conclude on the ED properties of this active substance with regard to human health. An ad hoc follow-up was opened to conclude on professional exposure assessment.

7. Discussion of Union authorisation applications

7.1 UA for product family containing propan-2-ol PT 2 (eCA NL)

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

7.2 UA for product family containing Permethrin PT 18 (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 family containing 1R-trans phenothrin PT 18 (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. Technical and guidance related issues

8.1 Update on Guidance development

This item was removed from the agenda.

8.2 HEAdhoc: Update to HEEG Opinion 15 on antifouling paints

ECHA SECR informed that the document had been discussed within HEAdhoc in a WebEx meeting after the comments made during WG-V-2019 on the indicative value for hands exposure for professional brush/roller. A few editorial changes were made to the document that was agreed by the WG. The document has now been published in the HEAdhoc website.

8.3 HEAdhoc: Professional manual dipping of wooden items (PT 8)

The member in the lead of the document presented the proposal. The WG supported including this methodology in the next version of Recommendation 6 - Methods and models, replacing the current entry No. 22 in Table 1.

8.4 Quantitative risk characterisation for sensitisers

The WG was requested to discuss the possibility of assessing the risk of sensitisation in a quantitative manner for treated articles that are classified as sensitisers due to an in-can preservative.

The CEPE and A.I.S.E representatives presented their proposal on an approach for quantitative risk assessment (QRA), also explaining why the family of isothiazolinones as preservatives is essential for paint products.

The members pointed out several methodological issues that have to be addressed if agreed to perform QRA for skin sensitizer preservatives, such as: the derivation of reference values; the fact that the current exposure models estimate systemic and not local exposure; the selection of a Point of Departure to be used for the dose-response descriptor; the assessment factors. In addition it was pointed out that induction is an irreversible effect, that elicitation requires lower levels of active substance than induction and human data on the elicitation are lacking for isothiazolinones. Furthermore, the substances in the isothiazolinones group can cross react and this has to be considered in the risk assessment of paint products along with the potential of aggregated exposure. Moreover, it was noted that sensitisation might be a permanent, life-long situation for specific individuals and therefore, the assessment has to be sufficiently conservative.

One member noted that the use of EC3 could be debated as the point of departure for QRA. While the local lymph node assay (LLNA) indicates the substance as a "strong" and not an "extreme" sensitiser, the specific concentration limit of 15 ppm was derived from human patch testing and not LLNA. In this case, the animal study informs of potency while human testing informs of prevalence.

A member also commented that the inhalation route may also elicit a sensitisation response and this has to be considered along with the dermal route.

It was asked whether the REACH guidance can be implemented in biocides too. The ECHA REACH expert replied that the REACH guidance is endpoint specific with focus on the adequacy of data for classification and it does not tackle the DNEL derivation.

In relation to the approach in the cosmetics sector, where the problem with isothiazolinones and skin sensitisation started, a member reported that the Scientific Committee for Consumer Products considers that QRA for skin sensitizers has to be done with precaution.

The Chair asked the members whether it is possible to reply whether it is acceptable to perform QRA for skin sensitisation. Some of the members clearly supported the proposal, whereas others pointed out that without proper assessment of the uncertainties, it is not possible to decide.

The Chair concluded that there is the need to further reflect, also noting the active input provided during the discussion. The SECR will inform of the way forward.

8.5 Revising the WG recommendation on in situ generated substances

ECHA SECR updated the WG on the project for revising the existing WG recommendation on in situ generated active substances. The topics that will be subject to discussion during the update have been already identified, noting that additional points may also be considered. ECHA SECR informed that a task force has been created and requested for further volunteers for contributing in the revisions.

The WG members welcomed the initiative and several questions were made regarding timing and organisation of the workload.

9. Any other business

9.1 Other information & lessons learned

The Chair informed that new combined timelines for active substance approval and union authorisation processes are available on ECHA website.

The Chair collected feedback from the WG participants on the WebEx meeting.

Annex 1 - Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
MAXIMILIEN Elisabeth (FR)
LORI Julia (FR)
BREEN Alan – alternate (IE)
WELTEN Angelique (NL)
LEŠER Vladka (SI)
Rapporteurs
TORDOIR Charlotte (BE)
LORENZETTI Stefano (IT)
ALMEIDA Francisca (PT)
MIKOLASKOVA Denisa (SK)
Flexible members
HAUZENBERGER Ingrid (AT)
HOELZL Christine (AT)
BRYS Kristel (BE)
HERREMANS Yannick (BE)
ROSSIER Nadine (CH)
BOYE PETERSEN Annika (DK)
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
HÄMÄLAINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
REY Marion (FR)
KOSE Serif (FR)
PUPIER Cindy (FR)
DEKOVI Edlira (IT)
KIWAMOTO Reiko (NL)
GAUSTAD Astrid (NO)
MIDHAUG Hilde Karin (NO)
ANDERSEN Hilde (NO)
GÓRECKI Roman (PL)
LITENS KARLSSON Sabina (SE)
ČEBAŠEK Petra (SI)
ROMAN Olha (SK)
ECHA Staff
RUGGERI Laura
ESTEVAN MARTINEZ Carmen
DAMSTEN Micaela
PAPADAKI Paschalina
ANTAL Diana
VAN DE PLASSCHE Erik
VASILEVA Katya
VAN DER LINDEN Sander
OLIVERO Roberto
ROSSI Laura
Applicants
Thor
Lonza
Nouryon
Koppers
Belgagri
Veltek Associates Inc
Aero-Sense
Aqualution Systems Ltd
Exponent
Stakeholders
VAN BERLO Boris (CEFIC)
LEROY Didier (CEPE)
Experts: BROCK Anna, KVERNSTUEN Johnny, KERN Petra, WATT Ian
Advisors
LEPAGE Anne (BE)
MANI Orlando (CH)
KNEUER Carsten (DE)
PEISER Matthias (DE)
JENSEN Stine (DK)
GOUR Annabelle (FR)
BOITIER Caroline (FR)
BORGES Teresa (PT)