Final minutes of the Working Group meeting IV in 2023

Analytical methods and Physico-Chemical properties and Physical hazards (APCP)

(Meeting date: 7 December to 13 December 2023 – hybrid meeting)

2 April 2024

1. Welcome and apologies

The meeting was a virtual meeting. The Chair welcomed the participants of the working group meeting. 36 members, 8 advisors and 5 stakeholders were registered in the meeting. The list of registered participants and observers can be found in annex I to the minutes.

Participants of the working group meeting were informed that the BPC code of conduct applies to this meeting and that the meeting is not recorded and any recording is not allowed.

2. Administrative issues

The SECR reminded about the procedure for appointment of new and replacement members and the security rule for connecting to the meeting.

The chair shared some reflections on the purpose and goal of the working group meetings.

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 agenda was agreed without modification.

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

The Chair invited all working group 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 I 2023

In addition to some clerical corrections, one text proposal on the minutes of WG III 2023 was made. The working group members reviewed and agreed on the proposal. SECR had added the results of the ad-hoc follow-up to the draft minutes. It was questioned by the WG whether it is correct to include the outcome of the ad-hoc consultation into the minutes of the previous meeting. SECR clarified that this practice is according to the procedure documented for active substances (point 25) and union authorisations (point 19).

The working group agreed to the changes as proposed.

6. Active Substances

6.1. 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate (Prallethrin) PT 18

Please refer to the specific minutes of this agenda item.

6.2. Early WG, 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) PT6

Please refer to the specific minutes of this agenda item.

6.3. Early WG, sulfur dioxide released from sodium metabisulfite PT 6 (AU)

Please refer to the specific minutes of this agenda item.

6.4. Early WG, Bromide activated chloramine (BAC) generated from ammonium bromide and sodium hypochlorite PT 11 (AU)

Please refer to the specific minutes of this agenda item.

7. Union Authorisations

7.1. UA for a product family containing L-(+)-lactic acid PT 3

Please refer to the specific minutes of this agenda item.

7.2. UA for a product family containing Hydrogen peroxide PT 2,4

Please refer to the specific minutes of this agenda item.

7.3. UA for a product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine) PT 18

Please refer to the specific minutes of this agenda item.

7.4. Early WG UA for a product family containing Active chlorine released from sodium hypochlorite, PT 2, 3, 4 (AU)

Please refer to the specific minutes of this agenda item.

8. Technical and guidance related issues

8.1. Specification for applications with multiple reference sources

It was proposed to document the approach for setting a specification from multiple sources reported in the same application. The proposal was to consider all specifications for each source (mean +/- 3SD of 5 batches) and identify the "worst case" concentrations for the active substance and each impurity regardless of the source. These "worst case" concentrations combine the different sources and would make up the overall specification for the active substance dossier. The working group members agreed to the approach and clarified that in case there are multiple independent applications for the same active substance still multiple specification are required. It was also clarified that the proposed procedure leads to a specification, which has to be refined by TOX and ENV experts to arrive at a reference specification (= the scope of the active substance which was assessed and found to be safe in the approval).

There will be a concrete text proposal circulated for commenting and eventual inclusion in the APCP TAB.

8.2. Composition of carrier products

The proposal for handling of the composition of carrier products presented to the WG was:

"Considering that i) there is already a requirement to consider the composition of the biocidal product used for treatment for the composition and also ii) that a thorough description of the article and the treatment process (including weight ratio) should contain enough information to construct the composition of the complete treated article, it is proposed to require in all cases a composition based on the biocidal product used for treatment (without constituents lost during or after treatment and not present in the final treated article) together with a description of the article and the treatment process with enough detail to determine the composition of the final article provided to the user."

The proposal was discussed with focus on cases where the composition of the liquid (the biocidal product used for treatment or incorporation) after impregnation can be different from the liquid used for impregnation. An example would be where some components of the impregnating liquid would polymerise after treatment.

It was considered by several members that these kinds of effects could be understood to be already covered by the requirement to provide "*enough information to construct the composition of the complete treated article*".

One member argued that recital 21 of CA-NOV16-DOC.4.3.HANDLING CARRIERS_REV2_FINAL.DOC should be used to justify the proposal. Recital 20(a) requires the classification to be derived for "*the biocidal mixture/substance used in the product only*[1] *as it remains on the carrier material placed on the market*". Recital 21 requires the composition reported in the SPC (specifically the AS content) to be

[1] As the biocidal mixture/substance interacts at the surface of the carrier, its hazard properties will be relevant. (footnote from CA-NOV16-DOC.4.3)

consistent with the derived classification. In consequence recital 15 should also be consistent and require the composition to be in line with classification and SPC.

Highlighting recital 20 should also be sufficient to cover eventual changes in the composition like loss of solvent and polymerisation as it refers to "*as it remains on the carrier material*".

One member was indicating that the terminology should be checked for consistency and used precisely in the proposal.

The APCP WG agreed on the principle that the relevant composition of the carrier product is the one present on the carrier after impregnation complemented with sufficient information to derive the composition of the impregnating liquid.

Comments or proposals regarding this topic can be sent to BE APCP team.

Subsequently, an e-consultation could be used to agree on the concrete text.

Once agreed within the APCP WG, the concrete text is to be proposed to the CA meeting for discussion and agreement.

8.3. New APCP TAB entry proposals

Two proposals for new TAB entries were presented to the WG. These were regarding i) the information requirement for odour and ii) the information requirements for analytical methods for animal and human body fluids and tissues.

The first item triggered a longer discussion regarding the possible complications that could arise from the strict application of the proposed TAB entry. It was considered that the hazard and classification may not be known and potentially more testing may be required for waiving the odour endpoint. Several members expressed the view that it would be not desired to identify problems caused by the odour endpoint in the opinion forming phase. One member highlighted that for newly generated odour information we would only receive data on substances which are not harmful and therefore the value of this information to warn operators from danger is limited. However, it was also pointed out that this endpoint is a core data requirement in the BPR and cannot be discarded. Finally, the working group accepted the text as proposed. If the application of the new entries leads to unreasonable results, amendment of the entry will have to be discussed in the WG.

The second item was introduced with an emphasis on the fact that while the guidance requires an analytical method for "toxic and very toxic" substances, this does not preclude that an analytical method may also be required in other situations. Therefore the interpretation on "toxic or very toxic" according to Annex VII of CLP does not restrict the possibility to request analytical methods in body fluids if this is found to be relevant. The working group supported the inclusion of the proposed text in the APCP TAB.

9. AoB

9.1. Exchange on problems in evaluation (closed session)

The working group discussed generic problems observed by members during evaluation to get advice or hear opinions from the members of the working group. No decisions can be taken during this item.

9.2. Training on Read-across Assessment for Organic Peroxide Classification

The working group received a bespoke training delivered by Mr. Wim Mak (TNO) focussing on the classification procedure for organic peroxides on the specific example of peracetic acid (PAA) based mixtures.

The training gave an overview of the classification flowchart and the different tests required, an estimation how the different tests react to changes in the composition and a discussion of read-across possibilities for the different tests specifically for PAA mixtures. The recommendation was to expect little impact of small compositional changes for the detonation and deflagration tests, expect impact specifically from the presence of strong acids but also other minor components and impurities (metal ions) for the explosive power, heating under confinement and SADT tests.

The training also touched upon the subject of possible classification of aqueous PAA formulations as organic peroxide type G.

9.3. Other information

The working group was informed about the timelines for 2024 related to the working group.

The SECR made available a collection of final working group minutes with an excel spreadsheet to facilitate searching.

Summary of e-consultations

There have been 7 e-consultations started after WG III 2023 which were shortly summarised by the respective members.

Annex 1 - List of attendees registered for the meeting

Country	Member state participant	
AT	Dominik	Altmann
AT	Natalie	Hofmann
AT	Erich	Neuwirth
BE	René	Bay
BE	Anastasia	Burmistrova
BE	Minh-Dung	Dang Thy
BE	Steven	Fauconnier
BE	Yannick	Herremans
BE	Samuel	Huerga-Fernandez
BE	kim	Swennen
CH	Michael	Aeschbacher
CH	Amandine	Courdouan Merz
CZ	Martin	Vlasak
DE	Melanie	Dobelmann
DE	Anne	Miks
DE	Kristof	Seubert
DE	Anna Maria	Zellermann
DE	Ulrike	Mühle
DE	Tobias	Deden
DK	Jeppe Juhl	Christiansen
DK	Katrine	Domino
EE	Imre	Vallikivi
EL	Stavroula	Batistatou
EL	Ioulia	Moschou
EL	Evangelia	Tzanetou
EL	Panagiotis	Gatos

ES	DAVID	Cano
FI	Katariina	Vuorensola
FR	François	Lutz
FR	philippe	Weber
FR	Thérèse	Six
IT	Lucilla	Cataldi
NL	Cornelia	Blaga
NL	Peter	Van Rijnsbergen
NL	Alena	Bourke
NL	Marianne	Pouwels
NL	Sabine	Kruidhof
NL	Inge	Storm
NO	Ingrid	Gjerde
NO	Marianne Stave	Sekkenes
PL	Magdalena	Juraszek
PL	Anna	Horczyczak
SE	Anh	Johansson
SE	Göran	Marsh
SE	Christoffer	Österwall
SI	Špela	Velikonja Bolta
SI	Klavdija	Zirngast
SK	Zuzana	Drabová Kušíková
SK	Michal	Porubiak
trainer		
(TNO)	Wim	Mak

Accredited Stakeholder Organisations (ASOs)		
Arxada	Paul	Wheeler

Ecolab	Laura	Pedraza
A.I.S.E	Marie	Régnier

Applicants
Sumitomo Chemical
Endura S.p.A.
exeo Strategic Consulting AG
THOR GmbH
Merck KGaA
ICL Europe Coöperatief U.A.
SCC GmbH
Novadan ApS
Diversey Europe Operations B.V.

ECHA staff
Uphoff Andreas
Marcon Eva

WG-IV-2023
Final minutes
12 March 2024

Minutes of Efficacy WG-IV-2023

5, 7 and 13 December 2023

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 Efficacy Working Group (EFF WG) meeting and informed them that this meeting is split into three separate days. 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 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 and FR had sent comments on the EFF WG-III-2023 draft minutes. The revised draft minutes of WG-III-2023 were agreed at the meeting.

6. Discussion of active substances

6.1 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) PT 18 (eCA EL)

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

6.2 Early WG, DBNPA, PT12 (eCA DK)

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

7. Discussion of Union Authorisations

7.1 UA for a product family containing L-(+)-lactic acid PT 3 (eCA DK)

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

7.2 UA for a product family containing Hydrogen peroxide PT 2,4 (eCA NL)

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

7.3 UA for a product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine) PT 18 (eCA DE)

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

7.4 Early WG, UA for a product family containing Active chlorine released from sodium hypochlorite, PT 2, 3, 4 (eCA NL)

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

8. Article 75(1)(g) requests

8.1 Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1 and 3:2), PT 6, 13 (eCA AT)

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

8.2 Formic acid, PT 6 (eCA BE)

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

8.3 1,2-Benzisothiazol-3-(2H)-one (BIT), PT 6, 13 (eCA ES)

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

9. Technical and guidance related issues

9.1 TAB update - Tiered approach to testing preservatives (DE)

Revised TAB entry 17 was introduced by DE. There were some comments from the WG members related to short-term preservation of a maximum of 6 weeks, proper phrasing of omitting tier 2 tests, or omitting the ageing, soiling in curative treatment and accelerated ageing at elevated temperature as more favourable protocol.

The following agreements were made regarding:

- short-term preservation - the defined maximum period of 6 weeks will be removed. It was proposed initially based on a test running no longer than typically 4 to 6 weeks. As in principle, this period should be covered by biological testing, which, however, can be longer than 6 weeks. The WG members were in favour of removing this specific period and not defining the maximum time for short-term preservation.
- proper phrasing, i.e. omitting the tier two test, or omitting ageing - it was decided to discuss it further during one of the next WG meetings to avoid potential confusion during the opinion-forming process.
- curative treatments - the text in brackets referring to soiling will be removed as the WG did not see any valid reason to mention it specifically. It was pointed out that in such a case all other factors influencing efficacy should also be mentioned. Additionally, it was decided to add a sentence that the choice of ageing method should be justified regarding the use, ageing procedure, storage manner, rationale behind, etc.
- favouring accelerated ageing at elevated temperature – this sentence will be deleted. Both procedures (accelerated ageing at elevated temperature or storage at ambient temperature) have rather equal value and it is up to the applicant to decide.

It was also pointed out that appendices 6 and 9 in the main guidance might be not in line with the current TAB proposal (some discrepancies may appear) and this needs to be taken into account by the applicants and evaluating MSs. On a general note, it was pointed out that it would be beneficial to revise/develop the chapters related to preservatives (except PT11/12 recently published).

The agreed TAB entry is presented below:

17. PT 6-13: Tiered approach to testing preservatives

Note: This TAB is not applicable to PT 8.

What efficacy tests are required for authorisation of biocidal products belonging to Main Group 2: Preservatives?

In accordance with the Guidance on the BPR, Volume II Efficacy - Assessment and Evaluation, Parts B+C, a tiered approach is to be followed for preservative efficacy testing.

Nevertheless, all three test tiers are not systematically necessary. Appropriate and valid tier 2 tests supporting the claimed use can be submitted to demonstrate the efficacy of a preservative biocidal product. In this case, tier 1 tests can be waived. For each intended use, efficacy needs to be demonstrated in tier 2 tests, in at least one relevant matrix and against all intended target organism groups.

Regardless if only tier 2 or both tier 1 and tier 2 tests have been submitted, the efficacious dose will always be derived from tier 2 tests only. In case tier 3 tests (field tests) are submitted instead of tier 2 tests, additional laboratory evidence (tier 1 tests) needs to be submitted and both the tier 3 test and the laboratory evidence will be taken into account when setting the efficacious dose, unless the applicant can comprehensively justify why it is not possible to mimic relevant basic environmental conditions in a laboratory setting.

What are the requirements for tier 2 efficacy tests for preservatives? – Part 1: Simulated ageing.

According to the Vol. II, Parts B+C efficacy guidance efficacy should be demonstrated under "real life conditions". For tier 2 tests, a special focus is put on simulating ageing[1] of the tested system (both treated matrix and untreated control). Typically, the following procedures/factors should be employed to generate tier 2 data for preventive treatment, depending on the specific uses applied for and the potential efficacy-reducing factors that can be expected in these uses[2]. The choice of ageing methods used in the respective efficacy tests has to be justified by the applicant based on the expected in-use conditions.

- PT 6 – Accelerated ageing of the claimed treated matrix at elevated temperatures or storage at ambient temperature[3].
- PT 7 – Exposure to air (to allow the evaporation of volatile components), humidity, UV irradiation, leaching in water, accelerated ageing at elevated temperatures, or a relevant combination thereof[4]. Alternatively, outdoor ageing, if relevant.
- PT 9 – As for PT 7. For treated textiles, washing cycles should be considered if relevant.
- PT 10 – As for PT 7.
- PT 11 – Usually not relevant.
- PT 12 – Usually not relevant.
- PT 13 – Accelerated ageing of the claimed treated matrix at elevated temperatures or storage at ambient temperature and addition of appropriate soiling[5].

In certain cases, ageing procedures can be omitted if ageing is demonstrably not relevant for the specific use, for example:

- For curative treatment, ageing generally is not relevant and can be omitted when generating the efficacy data.
- Products intended for short-term preservation (e.g. short-term preservation of white water in PT 6) would not require tests with an aged matrix if the article is preserved only for periods that are covered by the submitted biological testing.
- When the product is dosed into the treated matrix continuously or repeatedly in intervals shorter than the duration of the biological testing (such as typically in PT 11 or 12).

In any case, when ageing procedures are waived, a justification should be included in the respective dossier.

[1] In this document, the generic term "ageing" includes all relevant environmental factors that can cause loss of the biocidal effect in a treated matrix, such as e.g. weathering, UV exposure, extended storage, leaching, soiling, or washing and cleaning regimens.

[2] This is a non-exhaustive list. Other ageing modes, which have not been named here, may be necessary depending on the individual use and ageing factors encountered in that context.

[3] Ageing protocols for the test matrices should be adapted from section 2.6.4.1 on storage stability in Volume I (Parts A/B/C, version 2.1) of the BPR guidance. Storage at any of the combinations of temperature and test duration described in the guidance section on accelerated storage or at ambient conditions for at least 6 months is considered sufficient to demonstrate efficacy within the usual shelf life (including periods longer than 6 months) of any preserved articles (from the production of the treated article until the first opening).

[4] Ageing protocols already established for paints/coatings (e.g. ASTM D4587, EN ISO 16474-2/3, BS 3900-G6 Appendix E) or wood preservation (e.g. EN 73, EN 84, EN 152 Annex F) can also be adapted to other solid matrices.

[5] A standard setup for accelerated ageing at elevated temperatures could be 7 days at 40 °C. Soiling should always be added and can be performed as in IBRG FFG16-001.4: add 1% of 1% yeast extract solution.

After the required ageing procedures have been performed[6], the standard challenge test described for tier 1 in the guidance and its appendices (e.g. IBRG PDG 16-007 for the preservation of aqueous-based products in PT6) could be performed to generate tier 2 data.

What are the requirements for tier 2 efficacy tests for preservatives? – Part 2: Other aspects.

In certain cases, only one challenge can be considered sufficient, if multiple challenges are not relevant for the specific use, e.g. a PT 6 product is used right before packaging for the preservation of a treated article in a tightly sealed container until the first opening and the treated article is not intended to be preserved after opening the can.

Furthermore, care should be taken to simulate in-use conditions in tier 2 tests. Hence, solid matrices should usually not be tested on agar plates in tier 2 tests. Agar holds high amounts of available water, while humidity in most real-life applications is a limiting factor on bioavailability and thus efficacy of biocides. Furthermore, even very pure agar often contains unspecified amounts of nutrients that are nevertheless sufficient to support microbial growth. If it is necessary to simulate soiling that would cause biological growth in practice, it should be added separately in a controlled way.
Likewise, biocides for liquid matrices must be tested in a matrix that is relevant for the respective use. To simulate soiling that would be encountered in the in-use conditions, very low amounts of defined nutrients may be added. In some cases, a combination of ageing and soiling will be appropriate. Testing of preservatives in microbiological nutrient media is not relevant to demonstrate efficacy and should not be employed.

9.2 TAB proposal - How to determine the duration of efficacy of the disinfection bath (NL)

The revised TAB proposal was introduced by the NL. To facilitate the discussion DE clarified some proposals for amendments, which were sent shortly before the meeting. The proposed amendments concerned all similar uses to which this TAB entry should apply even if they are not yet explicitly mentioned in the EFF guidance. It was proposed that the specific examples of items should be mentioned only at the beginning of the proposal. In addition, concerning the alternative method for determining the duration of the claimed efficacy of the bath, an adapted less specific wording was proposed to cover all the potential uses that can be included. Moreover, using the most difficult organism to kill per claimed organism group should only take place if efficacy has already been demonstrated for the one-time use (i.e. with fresh disinfection solution), otherwise, all test organisms requested by the relevant EN standard should be tested. Furthermore, for consistency reasons, the EN standards should be identical to the ones used for one-time use.

The discussion was rather limited, and no agreement could be reached, a few issues were raised by the WG members, such as:

- Soiling, some members pointed out that not only the concentration of the active substance but also soiling brought by the submerged, disinfected items should be taken into account in each of the disinfection cycles as increasing the amount of organic load will impact the efficacy of the disinfectant. Therefore, soiling should be added to the proposal, at best to the use conditions, or somewhere in the text;
- Different options were proposed to address repeated use of disinfection baths, e.g. measurement of the amount of soiling after disinfection followed by subsequent efficacy testing that covers the measured amount of soiling, or applying a higher concentration of an active substance at the beginning (before disinfection starts) and checking if the concentration of the active substance after the duration of use of the bath is not lower than derived from testing. However, measurement of only the active substance concentration after several passages, although proposed by the current guidance, sounded doubtful for some WG members as it may not reflect

[6] In some cases, an untreated matrix may become spoiled by microbial growth during the ageing process and will therefore not be suitable for use during the challenge test. Such cases should be recorded and the affected sample(s) should be replaced by a fresh sample of the same matrix as the untreated control for the challenge test.

the efficacy of the disinfectant. It seems that the preferred option for some WG members would be to check after the duration of use of the bath if the disinfectant is still able to reach the appropriate pass criteria;
- Pass criteria, it was pointed out that concerning the respective pass criteria in EN standards in some cases adaptations may be needed. However, it was also indicated that they should not be lowered, the decision should be case-by-case based as this TAB proposal is quite general;
- The sentence: *"It is advisable to discuss the test set-up with the eCA or within the WG EFF"* should be amended as for applications at the national level the reference MS and the CG are the relevant bodies to be consulted.

The NL as the leading MS requested to suspend the discussion. It was proposed to revise the current version and before the next discussion comment on it by the EFF WG via e-consultation.

9.3 TAB proposal – Evaluation of PT 18 products against tropical (unicolonial) ants (DE)

This agenda item was moved for discussion to the WG-I-2024 due to the time constraints.

9.4 Field of use - joint session of HH and EFF WGs (AT)

The proposed revision of the claim matrix for PT 2 and PT 4 in Appendix 1 of Vol. II, Parts B+C efficacy guidance was started in an e-consultation initiated in August 2023 by AT. The rationale is that the information in the *'area of use'* column in the current claim matrix is insufficient to determine the relevant human exposure scenarios. AT presented the revised Appendix 1 with the following changes:

- Word format is proposed to be replaced by Excel;
- column 'Product description' is proposed to be deleted;
- column 'Use area' is proposed to be deleted;
- two above-mentioned columns will be replaced by a new column 'Field of use' containing different areas of use with more detailed descriptions;
- in each PT, different sections are kept, e.g. hard surfaces and toilet bowl;
- in some sections the exemplary users are proposed to be split depending on the user type, indicating users with 'a' and 'b';
- in the column 'User type' for some areas of use additional user type is proposed, or user types are limited/amended.

It was proposed to keep the Excel file as a living document to be easily updated.

The HH/EFF WG members welcomed the idea to specify the 'field of use' description in more detail. The EFF WG members pointed out that Appendix 1 is rather obsolete and the information concerning efficacy, such as obligatory/optional target organisms, appropriate methodology, and appropriate performance standard relevant to the target site can be removed as it is already available in different places of Vol. II, Parts B+C.

It was pointed out that while the description of use areas does not give sufficient information to be used in HH exposure assessment, this claim matrix was developed for efficacy purposes and potential modifications may not bring a good solution for HH assessment but will complicate the evaluation of efficacy, e.g. such detailed description may result in products being authorised for a very small area of use. Concerns were raised that this might lead to an unnecessary increase in the number of uses which would complicate evaluation and extend the SPC.

Notations such as '//' and 'and//or' were suggested to be clarified. It is also not clear whether the applicants need to claim everything within the bracket or can also claim only some of the use areas in the brackets.

It was proposed either to have two separate tables for the EFF and HH or to revise the current Appendix 1 by deleting the columns related to efficacy and using a modular system, which would enable having several use areas within one use. The latter option could facilitate having sufficient information on the use for HH exposure assessment and also sufficient for the evaluation of efficacy. This would also prevent an unnecessary extension of the SPC.

Another proposed option was to remove Appendix 1 from the EFF guidance and turn it into a more flexible "TAB" entry.

Some HH WG members had concerns regarding handling of updates of this Appendix from the EFF and HH point of view (e.g. if a new application method will be added), what category of users should be mentioned in the 'User type' column (it was proposed to delete the trained professional user). It was also asked if other columns should also be revised.

AT will revise the document based on the discussion. This revised version will be shared with the EFF/HH WG members and ASOs for commenting in January 2024 and the next discussion is foreseen at WG-I-2024 in March[7].

10. AOB

10.1 Other information

A brief update on the upcoming EFF WG-I-2024 meeting was provided including the deadlines for the early WG discussion requests and working documents submission. In addition, ECHA shared several updates related to:

- guidance update,
- status of e-consultations,
- timelines for the opinion-forming phase for the relevant PFs for applications for active substances approval and Union authorisation applications,
- some remarks concerning the opinion-forming phase for active substances and biocidal products dossiers.

The Chair asked also for remarks and suggestions for improvement regarding the opinion-forming phase and organisation of the WG meetings. One question was raised regarding the anonymised saving of the RCOM. It would be beneficial for the MSs to see who made the comments (internally and between the MSs). ECHA will investigate this possibility and come back with the information during the next meeting.

10.2 Ongoing developments of virucidal claims (closed session)

DE introduced this topic mainly to raise awareness that based on the recent publication there is a concern about specific viruses, mainly parvoviruses or hepatitis E virus, which pose a challenge for common disinfectants used in research or medical laboratories.
If such viruses are claimed, to prove efficacy against them may require additional test organisms than recommended in ECHA guidance for testing virucidal activity in PT2 (healthcare). In the presented publication additional virucidal claim is suggested, called virucidal activity plus, and Murine Parvovirus is proposed as an additional test organism in phase 2, step 2 test. The WG discussion aimed to share experiences from the national or EU levels concerning such specific claim(s) and the approaches taken. The EFF WG members did not encounter such specific claims yet. Information was given that currently, CEN is discussing the potential re-naming of different levels of virucidal activity in different use areas. The WG Chair will contact CEN to get more detailed information.

10.3 Feedback from the e-consultations (closed session)

AT, SI and SK provided brief feedback about the results of the finalised e-consultations.

[7] Post-WG note: The discussion is currently expected to take place at WG-II-2024.

Annex 1

Efficacy WG attendees

AT	Bernhard	WIDHALM
AT	Dominik	ALTMANN
BE	Abla	ANENE
BE	Anastasia	BURMISTROVA
BE	ANNE	LEPAGE
BE	Jennifer	PIROTTE
BE	Minh-Dung	DANG THY
BE	Natania	PEELMAN
CH	Eliane	WANDELER
CH	Frédéric	SANS-PICHÉ
CH	Gérard	DONZÉ
CH	Manuel	RUSCONI
CH	Margrith	MEIER
CH	Rebekka	BAUMGARTNER
CZ	Roman	SVEJSTIL
DE	Irina	JANSEN
DE	Juliane	FISCHER
DE	Martin	KRÜGER
DK	Charlotte Cleyton	JØRGENSEN
DK	Magnus Gammelgaard	BERTELSEN
EL	Athanasios	GIATROPOULOS
ES	Cristina	PORTELA
ES	María Luisa	GÓNZALEZ
ES	Natividad	PEREIRO
FI	Elina	RYDMAN
FI	Timo	NIEMINEN
FR	Catherine	BILLAULT
FR	Isabelle	ATTIG
FR	Nabila	HADDACHE
FR	Yann	MAXIMILIEN
IE	Aoife	OWENS
IT	LUCILLA	BALDASSARRI
IT	Maria Beatrice	RONCI
LV	Linda	MEZULE
NL	Bas	DEKKERS
NL	Sonja	WARMERDAM
NO	Karina	PETERSEN
NO	Marianne Stave	SEKKENES
NO	Sara	KJÆRVIK
SE	Bengt	ÅSLING
SE	Diana	POSLEDOVICH
SI	Darja	DUH

SK	Emese	DANADAIOVÁ
SK	Juliana	JAŠŠOVÁ

ECHA Staff	
Katarzyna	Szymankiewicz (Chair)
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EUROLAB	Carolyn	BURNEY
EUROLAB	Martina	RAZZABONI
EUROLAB	Katrin	STEINHAUER
A.I.S.E	Elaine	BLACK
A.I.S.E	Hannah	CORNER
CEFIC	Jules	BOSSERT
CEFIC	Verona	SCHUMACHER
A.I.S.E	Mara	MORENO
A.I.S.E	Marie	DARRIET

Applicants
Endura S.p.A.
Exeo Strategic Consulting AG
Sumitomo Chemical (UK) PLC
Arrow Regulatory
ICL Europe Cooperatief U.A.
Microbial Control (Switzerland)
Diversey
Novadan ApS
SCC GmbH
Lubrizol Deutschland
Vink Chemicals GmbH & Co. KG
Fraunhofer ITEM
BASF SE
Exponent International Ltd

Environment WG-IV-2023

Final minutes

11-12 December 2023

Minutes of Environment WG-IV-2023

Including TAB entries for revision in Appendix I

11-12 December 2023

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 53 members, advisors or rapporteurs registered for the meeting. One representative from accredited stakeholder organisation registered for the meeting, with two additional experts for their relevant item. Applicants were registered for their specific substance discussions.

2. Administrative issues

SECR informed on several administrative issues.

3. Agreement of the agenda

The Chair introduced the draft agenda and explained the removal of item 8.2. The WG was invited to add any additional items. The agenda was agreed without changes.

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

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None were declared.

5. Agreement of the draft minutes from WG-III-2023

The revised minutes were agreed without any further changes. One MS remarked that some revised minute(s) no longer showed the track changes compared to the previous version. Chair clarified that this was not intentional, and that in principle all changes should be clearly visible up to the final agreed version.

6. Discussion on active substances

6.1 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin) PT 18 (EL)

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

Action: AHF to clarify degradation in soil and/water-sediment and information on metabolites

6.2 Silver zinc zeolite, PT 2, 7, 9 - ED assessment only (SE)

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

Action: None

6.3 Early WG, DBNPA, PT12 (DK)

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

Action: None

6.4 Early WG, Eucalyptus citriodora oil, hydrated, cyclized in PT 19 (CZ)

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

Action: None

6.5 Early WG, Degradation of 2-phenylphenol in pig manure PT 3 (NL)

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

Action: Follow-up discussion in a dedicated expert group with representatives from NL, FR, DE and SECR

7. Discussion of Union Authorisation cases

7.1 UA for a product family containing L-(+)-lactic acid PT 3 (DK)

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

Action: None

7.2 UA for a product family containing Hydrogen peroxide PT 2,4 (NL)

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

Action: None

7.3 UA for a product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine) PT 18 (DE)

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

Action: None

8. Technical and guidance related items

8.1 Revised (draft) Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (PT 18) (DE)

DE is currently revising ESD for insecticides, acaricides and products to control other arthropods for household and professional uses (PT 18) after the previous discussions. DE received over 600 comments, of which a large part falls outside of the scope of the ESD revision. Three technical aspects were discussed at WG IV 2023, and a dedicated expert group meeting for the remaining items is planned for 30 January 2024.

8.3 Update OC normalisation (DE/NL)

DE and NL presented the outcome of the recent e-consultation on the proposal regarding organic carbon normalisation in sediment. NL provided replies to the comments and additional discussion took place on options for refinement.

8.4 Chesar update

SECR provided an update on the Chesar Platform and showed a demo of the application. Beta testing will take place in Q1-Q2 2024. First testing by Biocides users is foreseen in the beginning of March 2024 (tentative). Version 1 is expected to go public Q2-Q3 2024. Several fate models have already been implemented in Chesar Platform (direct releases to soil and water; wastewater) and they are being tested internally. Scenario repository documents (PTs 1, 2, 4, 5, 6, 8, 9, 14, 15, 19, 22) and secondary poisoning applicability are currently under e-consultation for the ENV WG. In the future, Chesar Platform will be updated in line with new guidance and new TAB agreements, which is likely to have an impact on the schedule of new TAB entries publication. First discussions took place regarding the versioning of the tool and biocides guidance applicability. As for reporting from Chesar Platform, the tool – in its later releases – will generate tables for the purposes of environment exposure and risk assessment to facilitate CAR/PAR preparation. However, there may be changes to the layout of the tables and structure of the CAR/PAR templates.

9. AOB

9.1 Other information & lessons learned (SECR)

Live agenda

The Chair reminded the WG that since the previous WG a live agenda is available. Statistics show the live agenda is actively used.

E-consultations and early WG discussions

The Chair referred to the e-consultation and early WG document that is available on the BPC website. Please use the template when preparing e-consultations. For early WG, the same document can be used if considered useful. The members are reminded to report back the outcome of the e-consultation. If the e-consultation results in an early WG discussion, no separate reporting is expected.

Next WG meetings

The next WG is expected to be a virtual meeting with the following provisional timing of 11-22 March 2024. SECR reminded the members that as a principle, late registrations for WGs will not be handled. This concerns both members and applicants. Once the draft agenda is available, there should be around two weeks to register. Addition of agenda items for the next WG can be requested by 29 January 2024 (including early WG discussions). E-consultations intended to be discussed at ENV WG I 2024 should be (ideally) launched by 8 January if intended to be discussed at ENV WG I 2024, to provide enough time for commenting and preparation of the WG discussion.

Update on the ECHA Bee guidance

The Bee guidance has been adopted at BPC-49 and the CAs will discuss in December the exact applicability date. The guidance is intended to be published in Q1 2024. There are still discussions ongoing with COM and EFSA for a calculator toll and training based on the guidance.

PBT EG consultations

The Chair reminded the WG that where needed the PBT EG can be consulted and encouraged the WG to use this option. Please inform SECR (via BPC-ENVWG@echa.europa.eu) if you foresee any PBT EG consultation in 2024, preferable by 15 December 2023.

Need for dedicated AHEE meeting 2024

SECR has received several questions regarding future AHEE meetings. In 2023, most exposure items have been discussed at the WG, as the virtual meetings more easily allow inviting additional experts to the WG. However, some topics might benefit from an AHEE discussion before discussing the item in the ENV WG. MSs are invited to send topics for a dedicated AHEE meeting where they feel this would be beneficial.

OECD 308

During commenting for a.s. an issue was raised regarding DT50 derivation for water and sediment compartments from OECD 308 studies depending on adsorptivity of the substance. This specific topic was already discussed previously, but no harmonised approach was identified. SECR will launch an e-consultation to clarify the approach.

Clarification of term "white water" – PT12

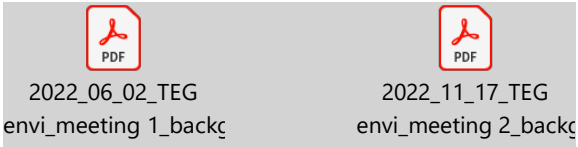
Questions regarding the use of the term "white water" for PT 12 uses were raised in BPC-49 and 82nd SCBP meeting. SECR clarified the definitions present in guidance documents and proposed that the assessments should clarify whether it refers to short or long circulation to avoid discrepancies. FR mentioned that they are planning to submit an e-consultation that includes this issue.

Appendices:

Appendix I: List of TAB entries as agreed upon by WG members

ECHA Secretariat note: Following the suggestions from WG members collected in the general minutes of WG-II-2023, the TAB entries originating from Chesar Platform discussions have been updated and agreed upon as follows:

The following TAB entries originate from the Chesar Platform discussion from the Topic Expert Groups (TEGs). The TEG meeting notes are given in the two embedded documents below.



ENV XXX Kp_{sed} and Kp_{susp} differentiation between freshwater and seawater compartments

Version 1 (WG-II-2023)

Chesar Platform will provide the possibility to enter separate solids-water partitioning coefficients, i.e., Kp values, for seawater and freshwater environments. By default, seawater Kp values will be set equal to freshwater Kp values (as assumed in EUSES), but they can be overwritten by the user (e.g., if measured values in seawater are available). The objective is to enable the differentiation of Kp values when different partitioning behaviour of the substance is expected between seawater and freshwater (mostly for ionisable substances and (metal)salts) due to different ionic strength or pH.

This change will affect seawater and sediment concentrations (PECs) at local and regional scale, and the corresponding risk characterisation ratios. It will only impact chemicals that have information on Kp for the seawater environment.

To account for this, the following adjustments are proposed for the Guidance on **BPR: Vol IV Environment Parts B+C**:

1. Water compartment is further specified as freshwater and seawater compartments

a) Equation 26 (p.57):

$$Kp_{comp} = Foc_{comp} \cdot Koc$$

$$with\ comp\ \epsilon\ \{soil, \boldsymbol{seawater\ sed}, \boldsymbol{freshwater\ sed}, \boldsymbol{seawater\ susp}, \boldsymbol{freshwater\ susp}\}*$$

Koc	partition coefficient organic carbon-water	[l.kg^{-1}]	Data set
Foc,comp	weight fraction of organic carbon in compartment comp	[kg.kg^{-1}]	Table 3
$Kp_{susp\ freshwater}$	solids-water partition coefficient in suspended matter in freshwater	[l.kg^{-1}]	
$Kp_{susp\ seawater}$	solids-water partition coefficient in suspended matter in seawater	[l.kg^{-1}]	
$Kp_{sed\ freshwater}$	solids-water partition coefficient in freshwater sediment	[l.kg^{-1}]	
$Kp_{sed\ seawater}$	solids-water partition coefficient in seawater sediment	[l.kg^{-1}]	
Kp_{soil}	solids-water partition coefficient in soil	[l.kg^{-1}]	

* Please note that the Chesar Platform tool uses the terminology of marine water and marine water sediment, which is considered interchangeable to seawater and seawater sediment, respectively, used here

b) Equation 27 (p.58):

$$K_{comp-water} = Fair_{comp} \cdot K_{air-water} + Fwater_{comp} + Fsolid_{comp} \cdot \frac{Kp_{comp}}{1000} \cdot RHOsolid$$

$$with\ comp\ \epsilon\ \{soil, \boldsymbol{seawater\ sed}, \boldsymbol{freshwater\ sed}, \boldsymbol{seawater\ susp}, \boldsymbol{freshwater\ susp}\}$$

$F_{water,\ comp}$	fraction water in compartment *comp*	[$m_{water}^3.m^{-3}$]	Table 3
$F_{solid,\ comp}$	fraction solids in compartment *comp*	[$m^3.m^{-3}$]	Table 3
$F_{air,\ comp}$	fraction air in compartment *comp* (only relevant for soil)	[$m_{air}^3.m^{-3}$]	Table 3
RHOsolid	density of the solid phase	[$kg_{dwt}.m^{-3}$]	Table 3
$K_{p,comp}$	solids-water partition coefficient in compartment *comp*	[$l.kg^{-1}$]	Equation 26
$K_{air\text{-}water}$	air-water partition coefficient	[-]	Equation 24
$K_{comp\text{-}water}$	compartment *comp*-water partition coefficient	[$m^3.m^{-3}$]	Equation 27

2. Clarification on the use of Kp_{susp} for Clocal calculation in freshwater (Equation 48, p. 82) and seawater (Equation 83, p. 119)

In the calculation of the local concentration in surface water ($Clocal_{water}$), for freshwater (equation 48, p.82) and seawater (equation 83, p.119), the respective solids-water partition coefficient in suspended matter (Kp_{susp}) should be used.

That is, in equation 48, for the calculation of the local concentration in surface water ($Clocal_{water}$), the $Kp_{susp\ freshwater}$ should be used, whereas in equation 83, for the calculation of the local concentration in seawater ($Clocal_{seawater}$), the $Kp_{susp\ seawater}$ should be used.

3. Clarification on the use of $K_{susp\text{-}water}$ for Clocal calculation in freshwater sediment (Equation 53, p. 84) and seawater sediment (Equation 87, p. 121)

In the calculation of the concentration in bulk sediment ($PEClocal_{sed}$), for freshwater (equation 53, p.84) and seawater (equation 87, p.121), the respective suspended matter-water partition coefficient ($K_{susp\text{-}water}$) should be used.

That is, in equation 53, for the calculation of the local concentration in freshwater sediment, the $K_{freshwater\_susp\text{-}water}$ should be used. Whereas in equation 87, for the calculation of the local concentration in sediment in the seawater environment, the $K_{seawater\_susp\text{-}water}$ should be used.

ENV XXX Consideration of natural background concentration for inorganics

Version I (WG-II-2023)

In the Guidance on BPR (Vol IV Environment Parts B+C, 2017), the natural background concentration is currently not considered when calculating PEClocal for the various compartments. To allow for the possibility to account for the natural background concentration in exposure (PEClocal) estimation, modified equations as indicated in the table below should be used instead of the existing equations.

The natural background concentration is relevant for naturally occurring substances like inorganics. Its addition to the exposure estimate (PEClocal calculation) may be relevant especially in cases where the PNEC values take into account the natural background concentration.

In the absence of specific information, natural background concentrations can be assumed to be zero. In the case of inorganic substances (e.g., iodine and silicon dioxide), for which the natural background concentration alone represents the limit value against which the PEClocal value is compared, the natural background concentration should not be considered in the PEClocal calculation.

New equations	**Replaces**	**Section in Guidance on BPR: Vol IV Environment Parts B+C**
$PEClocal_{freshwater} = Clocal_{freshwater} + PECregional_{freshwater} + Cnatural_{freshwater}$	Eq. 51 (p.83)	2.3.7.3 Calculation of PEClocal for the aquatic compartment
$PEClocal_{freshwater,ann} = Clocal_{freshwater,ann} + PECregional_{freshwater} + Cnatural_{freshwater}$	Eq. 52 (p.83)	2.3.7.3 Calculation of PEClocal for the aquatic compartment
$PEClocal_{seawater} = Clocal_{seawater} + PECregional_{seawater} + Cnatural_{seawater}$	Eq. 85 (p.120)	2.6.5.2 Calculation of PEClocal for the aquatic compartment
$PEClocal_{seawater,ann} = Clocal_{seawater,ann} + PECregional_{seawater} + Cnatural_{seawater}$	Eq. 86 (p.120)	2.6.5.2 Calculation of PEClocal for the aquatic compartment
$PEClocal_{sed,freshwater} = \frac{K_{freshwater\_susp-water}}{RHO_{susp}} \cdot Clocal_{freshwater} \cdot 1000 + PECregional_{sed,freshwater} + Cnatural_{sed,freshwater}$ (*)	Eq. 53 (p.84)	2.3.7.4 Calculation of PEClocal for sediment
$PEClocal_{sed,seawater} = \frac{K_{seawater\_susp-water}}{RHO_{susp}} \cdot Clocal_{seawater} \cdot 1000 + PECregional_{sed,seawater} + Cnatural_{sed,seawater}$ (*)	Eq. 87 (p.121)	2.6.5.3 Calculation of PEClocal for the sediment compartment

$PEClocal_{soil} = Clocal_{soil} + PECregional_{natural\,soil} + Cnatural_{soil}$	Eq. 69 (p.93)	2.3.7.5 Calculation of PEClocal for the soil compartment

(*) Note: $PEClocal_{sed}$ equations reflect also the changes indicated in TAB ENV #xx and #xx

Explanation of symbols

$Cnatural_{freshwater}$	natural background concentration in surface freshwater	[mg.l^{-1}]
$Cnatural_{seawater}$	natural background concentration in seawater	[mg.l^{-1}]
$Cnatural_{sed,freshwater}$	natural background concentration in freshwater sediment	[mg.l^{-1}]
$PECregional_{sed,freshwater}$	regional concentration in freshwater sediment	[mg.l^{-1}]
$Cnatural_{sed,\ seawater}$	natural background concentration in seawater sediment	[mg.l^{-1}]
$PECregional_{sed,seawater}$	regional concentration in seawater sediment	[mg.l^{-1}]
$Cnatural_{soil}$	natural background concentration in soil	[mg.kg^{-1}]

The newly proposed equation accounts for local, regional, and natural background concentrations when calculating $PEClocal_{soil}$, therefore when $PEC_{groundwater}$ (= $PEClocal_{soil,porewater}$) is derived from $PEClocal_{soil}$ using Equation 70 of the Guidance on BPR (Vol IV Environment Parts B+C, 2017), the resulting $PEC_{groundwater}$ already covers both local, regional and natural background concentrations present in soil porewater. In case $PECregional_{groundwater}$ and/or $Cnatural_{groundwater}$ values are available, i.e., as measured data, the modified $PEClocal_{soil,porewater}$ that allows for inputting $PEC_{regional}$ and $C_{natural}$ values can be used as follows:

$$PEClocal_{groundwater} = PEClocal_{soil,porew} =$$

$$= \frac{RHO_{soil} \cdot Clocal_{soil}}{K_{soil-water} \cdot 1000} + \frac{RHO_{soil} \cdot PECregional_{natural\ soil}}{K_{soil-water} \cdot 1000} + Cnatural_{groundwater}$$

Explanation of symbols

$PEClocal_{groundwater}$	predicted environmental concentration in groundwater	[$mg.l^{-1}$]
$Cnatural_{groundwater}$	natural background concentration in groundwater	[$mg.l^{-1}$]
$PEClocal_{soil,porew}$	predicted environmental concentration in porewater of soil	[$mg.l^{-1}$]
RHO_{soil}	bulk density of wet soil	[$kg.m^{-3}$]
$K_{soil\text{-}water}$	soil-water partitioning coefficient	[$m^3.m^{-3}$]
$Clocal_{soil}$	local concentration in soil	[$mg.kg^{-1}$]
$PECregional_{natural\ soil}$	regional concentration in natural soil	[$mg.kg^{-1}$]

Further clarification on what soil concentrations should be used for porewater calculations is given in ENV 237.

ENV XXX Using PEC regional sediment in PEC local sediment calculation and taking into account the natural background concentration

Version I (WG-II-2023)

In the Guidance on BPR (Vol IV Environment Parts B+C, 2017), the $PEClocal_{sed}$ is currently calculated from $PEClocal_{water}$ using the equilibrium partitioning approach as $PEClocal_{water} = Clocal_{water} + PECregional_{water}$ (Equation 51). The related equation for $PEClocal_{sed}$ (Equation 53) therefore does not allow for the use of e.g., measured data for $PECregional_{sed}$ as background concentration for the local scale if the exposure assessment is performed using the tonnage-based approach. By modifying Equation 53 to enable a separate input for local ($Clocal_{sed}$) and regional ($PECregional_{sed}$) releases, it would be possible to take into account the regional influence by means of e.g., measured data.

Therefore, Equations 53 (p. 84, Guidance on BPR: Vol IV Environment Parts B+C, 2017):

$$PEClocal_{sed} = \frac{K_{susp\text{-}water}}{RHO_{susp}} \cdot PEClocal_{water} \cdot 1000 \qquad \textbf{Equation 53}$$

should be replaced with:

$$\boldsymbol{PEClocal_{sed,freshwater} = \frac{K_{freshwater\_susp-water}}{RHO_{susp}} \cdot Clocal_{freshwater} \cdot 1000 + PECregional_{sed,freshwater} + Cnatural_{sed,freshwater}}$$

Explanation of symbols

$Clocal_{freshwater}$	local concentration in freshwater during emission episode	[mg.l^{-1}]	**Equation 48**
$PECregional_{sed,freshwater}$	regional concentration in freshwater sediment (total)	[mg.kg^{-1}]	**Section 2.3.7.7**
$Cnatural_{sed,freshwater}$	natural background concentration in freshwater sediment	[mg.kg^{-1}]	
$K_{freshwater\_susp\text{-}water}$	suspended matter-freshwater partition coefficient	[m^3.m^{-3}]	**Equation 27**
RHO_{susp}	bulk density of suspended matter	[kg.m^{-3}]	**Equation 20**
$PEClocal_{sed,freshwater}$	predicted environmental concentration in freshwater sediment	[mg.kg^{-1}]	

Similarly, **Equation 87** (p.121) concerning the marine water compartment is now replaced by the following one:

$$PEClocal_{sed,seawater} =$$

$$= \frac{K_{seawater\_susp-water}}{RHO_{susp}} \cdot Clocal_{seawater} \cdot 1000 + PECregional_{sed,seawater} + Cnatural_{sed,seawater}$$

Explanation of symbols

$Clocal_{seawater}$	local concentration in seawater during emission episode	[mg.l^{-1}]	**Equation 83**
$PECregional_{sed,seawater}$	regional concentration in seawater sediment (total)	[mg.kg^{-1}]	**Section 2.3.7.7**
$Cnatural_{sed,seawater}$	natural background concentration in seawater sediment	[mg.kg^{-1}]	
$K_{seawater\_susp-water}$	suspended matter-seawater partition coefficient	[m^3.m^{-3}]	**Equation 27**
RHO_{susp}	bulk density of suspended matter	[kg.m^{-3}]	**Equation 20**
$PEClocal_{sed,seawater}$	predicted environmental concentration in seawater sediment	[mg.kg^{-1}]	

ENV XXX Temperature correction - Calculation of vapour pressure and water solubility

Version I (WG-II-2023)

Equations 2 (p.32) and 3 (p.33) in the Guidance on BPR (Vol IV Environment Parts B+C, 2017) used to correct vapour pressure and water solubility values from a test temperature to the environmental temperature should only be applied for test temperatures in the range of 0°C to 40°C.

ENV 182 Temperature correction and molar activation energy (Ea) for biodegradation processes and hydrolysis in water

Version 2 (AHEE-3, WG-III-2020, WG-II-2023)

ECHA Secretariat note (14/12/2023): The draft of the revision of this TAB entry is pending revision due to parallel discussions for other guidance documents. We will keep the WG informed on the next steps once a conclusion regarding this issue has been taken for R16 and biocides.

ENV XXX Air default scenario (based on the new OPS tool)

Version I (WG-II-2023)

Following the study of Sauter et al. (2020), new standard factors have been proposed for the calculation of $Clocal_{air}$ and $PEClocal_{air}$ using the OPS gaussian plume model. The updated model builds its assumptions/settings on long-term annual average meteorological data collected during 2005-2014 in the Netherlands and a receptor height of 1.5 m. This induces changes to Section 2.3.7.2 of the Guidance on BPR Vol IV Environment Parts B+C as follows:

Equation 43			
$Cstd_{air}$	concentration in air at source strength of 1 $kg \cdot d^{-1}$	$[mg \cdot m^{-3}/(kg \cdot d^{-1})]$	$3.2 \cdot 10^{-4}$ (default) (the default value covers both the value of $3.18 \cdot 10^{-4}$ for gaseous substances and of $3.23 \cdot 10^{-4}$ for aerosol-bound substances) *
Equation 46			
$DEPstd_{aer}$	standard deposition flux of aerosol-bound compounds at a source strength of 1 $kg \cdot d^{-1}$	$[mg \cdot m^{-2}/(kg \cdot d^{-1})]$	$1.1 \cdot 10^{-2}$
$Depstd_{gas}$ (dep. flux)	deposition flux of gaseous compounds as a function of Henry's Law constant, at a source strength of 1 $kg.d^{-1}$	See Table 1	

* derived from the newly proposed standard values, i.e., the concentration of gaseous substances (27.5 $\mu g.m^{-3}$) and the concentration of aerosol-bound substances (27.9 $\mu m.m^{-3}$) in air at source strength of 1 $g.s^{-1}$, which were further divided by a factor of 86.4 (correction from the source strength of 1 $g.s^{-1}$ to the source strength of 1 $kg.d^{-1}$; 1 $g.s^{-1}$ = 86.4 $kg.d^{-1}$)

The values for $Depstd_{gas}$ (dep. flux) should be taken from Table 1 below (last column "Dep.flux") which shows the dependency of $DEPstd_{gas}$ on Henry's Law constant instead of the ranges currently provided in the Explanation of symbols table to Equation 46 in the Guidance on BPR: Vol IV Environment Parts B+C, Section 2.3.7.2. Note that if the Henry's Law constant falls in one of the ranges in the table below, the most conservative value should be used for the estimation of deposition.

Table 1

H ($Pa.m^{-3}.mol^{-1}$)	Dep.flux ($g.m^{-2}.s^{-1}$)	Dep.flux ($mg.m^{-2}.d^{-1}$)
≤ 1.0E-06	4.16E-09	3.59E-01
3.00E-06	4.15E-09	3.59E-01
1.00E-05	4.12E-09	3.56E-01
3.00E-05	4.05E-09	3.50E-01
1.00E-04	3.81E-09	3.29E-01
3.00E-04	3.26E-09	2.82E-01
1.00E-03	2.21E-09	1.91E-01
3.00E-03	1.23E-09	1.06E-01
1.00E-02	6.21E-10	5.37E-02
3.00E-02	3.84E-10	3.32E-02
1.00E-01	2.05E-10	1.77E-02
3.00E-01	9.40E-10	8.12E-02
1.00E+00	3.99E-11	3.45E-03
3.00E+00	2.34E-11	2.02E-03
1.00E+01	1.76E-11	1.52E-03
3.00E+01	1.60E-11	1.38E-03
1.00E+02	1.54E-11	1.33E-03
3.00E+02	1.52E-11	1.31E-03
≥ 1.03E+03	1.52E-11	1.31E-03

ENV XXX Volatilisation from soil at local scale

Version I (WG-II-2023)

To avoid unexpectedly high local soil concentrations for gaseous substances, the calculation of volatilization from soil at the local scale (i.e., k_{volat}) in Section 2.3.7.5.1 Indirect release of the Guidance on BPR: Vol IV Environment Parts B+C should be adjusted as follows:

Equation 54, i.e.:

$$\frac{1}{k_{volat\,i}} = \left(\frac{1}{kasl_{air} \cdot K_{air-water}/K_{soil-water}} + \frac{1}{kasl_{soil}}\right) \cdot DEPTH_i$$

should be replaced by equation describing the diffuse transfer from soil to air using the two-film resistance model (Mackay et al., 1992):

$$\boldsymbol{\frac{1}{k_{volat\,i}} = \left(\frac{1}{kasl_{air-soil} \cdot K_{air-water}} + \frac{1}{kasl_{soil-air} \cdot K_{air-water} + kasl_{soil-water}}\right) \cdot K_{soil-water} \cdot DEPTH_i}$$

Explanation of symbols

$k_{volat\ i}$	rate constant for volatilisation from soil *i*	[d^{-1}]	
$Kasl_{air\text{-}soil}$	partial mass transfer coefficient at the air-side (air-soil interface)	[$m.d^{-1}$]	**90**
$kasl_{soil\text{-}air}$	soil-air partial mass transfer coefficient (air-soil interface)	[$m.d^{-1}$]	**0.48, Equation 72**
$kasl_{soil\text{-}water}$	soil-water partial mass transfer coefficient (air-soil interface)	[$m.d^{-1}$]	**$4.8 \cdot 10^{-5}$**
$K_{air\text{-}water}$	air-water partition coefficient	[$m^3.m^{-3}$]	**Equation 24**
$K_{soil\text{-}water}$	soil-water partition coefficient	[$m^3.m^{-3}$]	**Equation 27**
$DEPTH_i$	mixing depth of soil type i	[m]	**Table 10**

The revised Equation 54 introduces a new symbol for the soil-air partial mass transfer coefficient (air-soil interface) that was changed from $Kasl_{soil}$ to $Kasl_{soil\text{-}air}$. This change is applicable also for pages 86, 102, and 104 of the Guidance on BPR (Vol IV Environment Parts B+C, 2017).

ECHA Secretariat note: Following the e-consultation in Collaboration (28/6-07/08/2023) and discussions at WG-II-2023 and WG-III-2023 (item 9-5), the TAB entry on sewer removal has been prepared as agreed during the WG-III-2023 meeting:

Removal of rapidly degrading/reacting substances in sewer systems prior to reaching a municipal STP

TAB ENV #39, version 2

To prevent being confronted with unrealistically high concentrations in an STP in the case of rapidly reacting/degrading substances entering wastewater, the removal in a sewer can be considered for:

- rapidly reacting substances or substances following fast abiotic degradation according to the CAR and/or
- substances for which biodegradation in the sewer is proven by OECD 314 A or similar literature or monitoring data and
- releases that take place to a municipal STP only (releases into industrial (onsite) WWTPs and rainwater sewers should not be taken it account)

The removal in a sewer is to be calculated as:

$$Csew,eff = \frac{Csew,inf}{1 + k * HRTsew}$$

Explanation of symbols

Csew,eff	sewer effluent concentration	[mg.L^{-1}]
Csew,inf	sewer influent concentration	[mg.L^{-1}]
k	sewer removal rate	[h^{-1}]
HRTsew	hydraulic residence time in sewer	1 h (default)

Appendix II: Environment WG attendees

Member state experts

Country	First Name	Last Name
AT	Christian	Kantner
AT	Iris	Buchner
AT	Lea	Breul
BE	Anne	Brasseur
BE	Céline	Leroy
BE	Samuel	Huerga-Fernandez
BE	Sofie	Tijskens
BE	Wiet	Raets
CH	Maria	A MARCA
CH	Petra	Kunz
CH	Tenzing	Gyalpo
CZ	Pavla	Lakdawala
DE	Jan	Achtenhagen
DE	Daniel	Frein
DE	Eleonora	Petersohn
DE	Jana	Schmidt
DE	Sascha	Setzer
DK	Jesper	Johannessen
DK	Nina Falk	Gregersen
DK	Henrik	Wennermark
EL	Theodosia	Fountouli
EL	Ioannis	Kandris
EL	Aikaterini	Boutsini
ES	Carolina	García Torrijos
ES	Elena	Ruiz López
ES	Myriàm	Martín Vallejo
FI	Jenni	Jokinen
FI	Jaana	Pasanen
FI	Sanna	Kaukoniemi
FI	Sari	Penttinen
FR	Fanny	HERARD
FR	Séléné	VERSTRAET
FR	Anne	Straczek
FR	Stéphanie	Alexandre
GR	Akrivi Chara	Mouzaki Paxinou
IE	Helena	Joyce
LU	Mathis	Wolter
NL	Merel	Van der Ploeg
NL	Peter	Okkerman

NL	ZhiChao	Dang
NL	Barry	MUIJS
NL	Els	SMIT
NL	Peter	van Vlaardingen
NL	Karlijn	Holthaus
NO	Karina	Petersen
NO	Sanne Helene	Kristensen
NO	Terje	Haraldsen
PL	Agnieszka	Podlaska
SE	Edda	Hahlbeck
SE	Isak	Holmerin
SE	Rina	Andersson
SI	Petra	Jeločnik Pelicon
SK	Simona	Lišková

Accredited Stakeholder Organisations (ASOs)

On behalf of	First name	Last name
Endura S.p.A	Ellen	Thom
SC Johnson	Wendy E.	Hillwalker
CEFIC	Jules	Bossert

Applicants and representatives

Sumitomo Chemical (UK) Plc
Endura S.p.A.
ERM
EU Silver Task Force
Microbial Control (Switzerland)
ICL Europe Cooperatief U.A.
Arrow Regulatory
Citrefine International Ltd.
LANXESS
Novadan ApS
SCC GmbH
Elanco Animal Health, Inc.

Human Health WG-IV-2023

Final minutes

12 March 2024

Minutes of Human Health WG-IV-2023

5, 7, 8, 12 December 2023

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 81 members or advisers registered, of which 15 were (alternate) core members. Two Commission representatives were registered for item 9.1. Three stakeholder representatives and one expert were registered. Applicants were registered for their case-specific discussions.

The list of attendees is given in Annex 1.

The Chair gave a brief presentation on the mandate and tasks for the WG, and the roles of the members, secretariat, applicants and Associated Stakeholder Organisations.

2. Administrative issues

SECR reminded that recording of the meeting is not allowed. All meeting participants need to be registered and late registration is not possible.

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.

One member declared a potential conflict of interest with regard to agenda item 6.1, and the member was excluded from the meeting for this agenda item.

5. Agreement of draft minutes from WG-III-2023

The minutes were agreed without further changes.

6. Active substances

6.1 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin), PT 18 (eCA EL)

The reference values were agreed as follows:

- $AEL_{long\text{-}term}$ 0.011 mg/kg bw/day
- $AEL_{medium\text{-}term}$ 0.011 mg/kg bw/day
- AEL_{acute} 0.023 mg/kg bw/day
- ARfD 0.05 mg/kg bw/d
- ADI 0.025 mg/kg bw/d

Assessment of human exposure was discussed and agreed, including dietary exposure.

6.2 Silver zinc zeolite, PT 2, 7, 9 (eCA SE)

The WG concluded that silver zinc zeolite does not meet the criteria for endocrine disruption. No proposals were made for performing additional studies.

7. Union authorisation applications

7.1 UA for a product family containing L-(+)-lactic acid, PT 3 (eCA DK)

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

7.2 UA for a product family containing Hydrogen peroxide, PT 2, 4 (eCA NL)

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

7.3 UA for a product containing N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine), PT 18 (eCA DE)

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

8. Technical and guidance related items

8.1 Field of use - Joint session of TOX and EFF WGs

The proposed revision of the claim matrix for PT 2 and PT 4 in Appendix 1 of Vol. II, Parts B+C efficacy guidance was started in an e-consultation initiated in August 2023 by AT. The rationale is that the information in the *'area of use'* column in the current claim matrix is insufficient to determine the relevant human exposure scenarios. AT presented the revised Appendix 1 with the following changes:

- Word format is proposed to be replaced by Excel;
- column 'Product description' is proposed to be deleted;
- column 'Use area' is proposed to be deleted;
- two above-mentioned columns will be replaced by a new column 'Field of use' containing different areas of use with more detailed descriptions;
- in each PT, different sections are kept, e.g. hard surfaces and toilet bowl;
- in some sections the exemplary users are proposed to be split depending on the user type, indicating users with 'a' and 'b';
- in the column 'User type' for some areas of use additional user type is proposed, or user types are limited/amended.

It was proposed to keep the Excel file as a living document to be easily updated.

The HH/EFF WG members welcomed the idea to specify the 'field of use' description in more detail. The EFF WG members pointed out that Appendix 1 is rather obsolete and the information concerning efficacy, such as obligatory/optional target organisms, appropriate methodology, and appropriate performance standard relevant to the target site can be removed as it is already available in different places of Vol. II, Parts B+C.

It was pointed out that while the description of use areas does not give sufficient information to be used in HH exposure assessment, this claim matrix was developed for efficacy purposes and potential modifications may not bring a good solution for HH assessment but will complicate the evaluation of efficacy, e.g. such detailed description may result in products being authorised for a very small area of use. Concerns were raised that this might lead to an unnecessary increase in the number of uses which would complicate evaluation and extend the SPC.

Notations such as '//' and 'and//or' were suggested to be clarified. It is also not clear whether the applicants need to claim everything within the bracket or can also claim only some of the use areas in the brackets.

It was proposed either to have two separate tables for the EFF and HH or to revise the current Appendix 1 by deleting the columns related to efficacy and using a modular system,

which would enable having several use areas within one use. The latter option could facilitate having sufficient information on the use for HH exposure assessment and also sufficient for the evaluation of efficacy. This would also prevent an unnecessary extension of the SPC. Another proposed option was to remove Appendix 1 from the EFF guidance and turn it into a more flexible "TAB" entry.

Some HH WG members had concerns regarding handling of updates of this Appendix from the EFF and HH point of view (e.g. if a new application method will be added), what category of users should be mentioned in the 'User type' column (it was proposed to delete the trained professional user). It was also asked if other columns should also be revised.

AT will revise the document based on the discussion. This revised version will be shared with the EFF/HH WG members and ASOs for commenting in January 2024 and the next discussion is foreseen at WG-I-2024 in March[1].

8.2 Transfer coefficients for dislodgeable residues for the refinement of livestock exposure calculations

The working group agreed that default tranfer co-efficients for dislodgeable residues:

- may be used for the refinement of oral livestock exposure via contaminated feed in contact with dried fluid,
- in the absence of feed-specific data, the value 60% for dried fluids on brown rough glazed tiles can be considered worst-case,
- should not be used for the refinement of dermal livestock exposure.

8.3 HEAdhoc: Revision of recommendation 15

The working group discussed the proposed changes and agreed to the more precise definition of the professional cleaner and the numerical definition of the surface area 'small surface' of 0.5 m^2. The WG also supported the two new scenarios 'Hotel guest bathrooms' and 'Private bathrooms at domestic dwellings' but did not agree to the proposed changes in the ventilation rate with specific air change/hour (ACH) for Tier 1 and Tier 2. Instead, a minimum of 2 ACH was suggested for worst-case conditions.

8.4 HEAdhoc: PT 14 product individually packed in LDPP/LDPE sachets

The working group discussed the acceptance of visual inspection to detect leaks in packaging as standard in storage stability tests. The position paper prepared by FR was supported, concluding that no skin exposure to the user is expected when handling rodenticide products if the product is wrapped in closed low density polyethylene (LDPE) or polypropylene (LDPP) sachets.

8.5 HEAdhoc: BEAT

Concerns have been raised that information from raw data used for the BEAT model will no longer be accessible as the model is no longer supported. SECR is currently not in the position to take over BEAT and asked whether it was an option for a CA to take over BEAT from the HSE. SECR volunteered to inquire with HSE whether there are any potential barriers to the ownership and transfer of the underlying data. Members are asked to inform SECR by email if they are interested in taking over.

9. Any other business

9.1 EN standards

[1] Post-WG note: The discussion is currently expected to take place at WG-II-2024.

SECR informed that the announced training on PPE/RPE and EN standards will be organised in February (post-WG note: now confirmed to take place on 15 February 2024).

SECR introduced the document, proposing ways forward to include EN standards where PPE/RPE are required. The members commented on the following aspects:

- The MSCAs would not be able to verify that the material, thickness of material, breakthrough times, filters etc. are adequate but this is generally the responsibility of the applicant. Selecting appropriate materials for a product composition can be challenging or impossible for MSCAs.
- There are only few standards for gloves and coveralls and the MSCAs will be able to check these, while there are much more standards for RPE.
- The EN standards and protection factors are not linked and there is no direct correlation between these. For example, only EN374 may be relevant for gloves but there are other parameters that are not defined by the standard – material, thickness, breakthrough time etc. Furthermore, the protection factor is not linked to the PPE/RPE only, but also to the way these are used.
- The reason for requiring the EN standards should be clarified.
- Specifying the EN standard does not guarantee that the PPE/RPE are appropriate, and it will not be possible for the MSCAs to specify the exact PPE/RPE with all details.
- There is concern on large unnecessary burden for the MSCAs, as the added value and increase in safety was questioned.
- To assign the details of the appropriate PPE/RPE, it will be necessary to know how the materials were tested and with which chemical mixtures, and the physical stress applied in testing and needed in use.

COM clarified that the overall objective is to ensure that when risk is identified, the means of protection are adequate to reduce the risk to an acceptable level. The applicants can provide this information and the MSCAs are asked to look into this and whether the applicant's proposal can be supported. The parameters that are important for ensuring the safe use of biocidal products should be verified. COM also referred to the Art 36 decisions that were provided to the WG earlier (see the annex to WGIV2023_9-1).

Conclusions:

To provide the necessary level of details for any PPE (including RPE) in biocidal product authorisation processes:

1) Where PPE is required, the applicants should specify these in the application by including a relevant standard where possible.
2) The current approach (eCA/refMS verifying the PPE proposed by the applicant) should be complemented by including a check of the applicability and correctness of the standards proposed for the PPE.
3) To enable this check, the eCA/refMS may request information from the applicant.
4) The detailed specification (material, breakthrough times etc.) of the PPE is the responsibility of the applicants and cannot be fully verified by the eCA/refMS.

The PPE should be stated in the SPC, including any standards if relevant. If a standard is not stated, the PPE has to be clearly specified by indicating e.g. the material, breakthrough time and protection factor.

These conclusions should be considered provisional because more expertise will be required and it may be necessary to revise the conclusions.

9.2 Other information

HEAdhoc

SECR proposed to the HEAdhoc members the possibility to introduce a knowledge exchange platform in Interact which allows national human exposure experts to exchange informal advice on human exposure related topics. The proposal was well received and the platform will be established.

Minutes search

All finalised WG minutes are now available in Interact under WG-IV-2023, "Final minutes search until WG-III-2023". SECR intends to provide the latest version under each coming meeting. This tool contains all minutes, including the confidential ones, and is therefore available only to MSCAs.

Next WG meetings

The provisional timing of the next WG meetings is as follows:

- 11-22 March 2024 (virtual)

  For this meeting, items should be requested to be included on the agenda by 29 January (including early WG discussions).

  An e-consultation should be launched by 11 January if intended to be discussed in this meeting.

- 10-20 June 2024 (provisionally physical/hybrid)

  For this meeting, items should be requested to be included on the agenda by 29 April (including early WG discussions).

  An e-consultation should be launched by 10 April if intended to be discussed in this meeting.

Annex 1
Human Health WG attendees

Country	Member state participant	
AT	Christine	Hölzl
AT	Angelika	Derler
BE	Yannick	Herremans
BE	Lies	Peeters
BE	Margot	Van Cauwenberghe
CH	Daniela	GOLDINGER
CH	David	Grünig
CH	Nadine	Rossier
CH	Manuel	Rusconi
CZ	Jan	Mikolas
CZ	Petr	Sedlak
DE	Kathrin	Bissantz
DE	Susann	Matthes
DE	Isabel	Günther
DE	Dagmar	Holthenrich
DE	Kristin	Herrmann
DE	Kathrin	Gottlob
DE	Andrea	Holzwarth
DE	Saskia	Klutzny
DE	Soyub	Rime
DE	Michael	Roitzsch
DE	Heiko	Schneider
DE	Annetta	Semisch
DE	Benedikt	Piorr
DK	Johannes	Buch
DK	Stine	Jensen
EE	Sandra	Käosaar
EL	Niki	Arapaki
EL	Dimitra	Nikolopoulou
EL	ANASTASIA	REPOUSKOU
EL	Chris	Anagnostopoulos
ES	Bárbara	Martín de Madariaga

ES	Eduardo	de la Usada Molinero
ES	José María	Sánchez
FI	Janne	Atosuo
FI	Anna-Maija	Hämäläinen
FI	Tuija	Hyvärinen
FI	Elina	Rydman
FI	Elina	Välimäki
FR	Arnaud	Gallier
FR	Aurélie	AUBIN
FR	VALERIE	BELLINGARD
FR	julia	lori
FR	Elisabeth	Maximilien
FR	Tiffany	AMSALLEM
FR	Perrine	Capdeville
FR	Elodie	Collin
IE	Alan	Breen
IT	Edlira	Dekovi
LU	Christina	Rohles
NL	Marcia	Bodero
NL	Angelique	Welten
NO	Hilde Mariken	Andersen
NO	Jorid	Frydenlund
NO	Astrid	Gaustad
PL	Justyna	Dudek-Nowak
PL	Roman	Górecki
PL	Monika	Ujma-Czwakiel
SE	Ifthekhar Ali	Mohammed
SE	Edda	Hahlbeck
SE	Karolin	Ask Björnberg
SE	Anna	Gräske
SE	Emma	Pettersson
SI	Nataša	Petrovič
SI	Vladka	Lešer
SI	Petra	Čebašek
SI	Katja	Verdnik
SK	Dávid	Dráb
SK	Vladimira	Polohova
SK	Oľha	Roman

Accredited Stakeholder Organisations (ASOs)		
AISE	Joanna	Kupny
PSCI	Tess	Renahan
CEFIC	Jules	Bossert
AISE	Marie	DARRIET
SK	Ružena	Pilišiová

Applicants
Diversey Europe Operations BV
Novadan ApS
SCC GmbH
Elanco Animal Health, Inc.
Endura S.p.A.
exeo Strategic Consulting AG
SUMITOMO CHEMICAL (U.K.) PLC
ARGUS INTERNATIONAL
Field Fisher Waterhouse LLP