WG-III-2016

Final minutes

29 September 2016

Minutes of WG-III-2016

23 – 31 May 2016

Meetings of the Analytical methods and physico-chemical properties, Human Health, Efficacy and Environment Working Groups of the Biocidal Products Committee

Minutes of Analytical methods and physico-chemical properties WG

WG-III-2016 (23-24 May 2016)

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. None accredited stakeholder organisation (ASO) was registered for this meeting.

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

2. Administrative issue

Presentations on the administrative matters and on the declaration of interest (DoI) were provided by ECHA for information.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the working group members to include any additional items under any other business.

Two additional agenda items were included under AoB:

- Residues in food and feed and MRL settings
- Number of reference sources and specifications are eligible
- Precursors of in situ generated active substances – reference source

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

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

5. Agreement of the draft minutes from WG II 2016

Comments on the draft minutes were received as follows:

Sodium hypochlorite: Italy, France

Calcium hypochlorite: Italy, France

Chlorine: Italy

Momfluorothrin: France

Peracetic acid: Finland

General agenda items: Italy

The comments have been included in the updated draft minutes, discussed and agreed by the working group members.

6. Follow up of previous working group meetings

6.1 Bromine chloride - Redefinition

At the WG meeting II in 2016 the working group members could not agree on the naming of the substance. Hence, an e-consultation with follow-up was agreed at WG II 2016. However, after further ECHA internal consultation it was concluded that a renaming of the substance is not necessary.

6.2 Piperonyl butoxide – Reference source and reference specification

The reference specification was updated by the eCA with the contribution of the environment and human health experts, relevant impurities and their maximum concentration level are clearly identified. The working group members agreed with the updated proposal. Hence, the reference source and reference specification are set.

7. Discussion on the active substances

7.1 Azamethiphos PT18

All open issues were discussed and agreed by the working group members. Further clarifications on the partition coefficient (logPow), identities of unknown impurities and the reference specification are requested.

7.2 Dichlofluanid PT21

All open issues were discussed and agreed by the working group members. Further clarification on the reference specification is requested.

7.3 Margosa extract PT19

All open issues were discussed and agreed by the working group members. Further clarifications on the vapour pressure and the toxicological and eco-toxicological relevance of certain constituents of margosa extract need to be provided.

7.4 Silicium dioxide (Silicium dioxide/Kieselguhr) PT18

All open issues were discussed and agreed by the working group members. Further clarifications on the reference specification and the analytical methods are requested.

7.5 Silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) PT18

All open issues were discussed and agreed by the working group members. Further clarifications on the analytical methods and the reference specification are requested.

7.7 OIT PT08

All open issues were discussed and agreed by the working group members. Further clarification on the analytical methods is requested.

7.8 PHMB (1600; 1.8) PT05

All open issues were discussed and agreed by the working group members. A further clarification on impurities is requested.

8. Technical and scientific issues

8.1 Polymeric substance with variable composition generated in situ

The industry representative was invited to explain her case on (a) active polymeric substance with variable compositions. A short discussion with exchange of opinions and possible solutions took place but no concrete decision was taken. Industry was advised to stay in close contact with the future possible eCA and provide more specific proposals for an application for the approval of the active substance(s) which can be discussed at the other working groups and policy level too.

8.2 Polymeric substance not generated in situ

The industry representative was invited to explain his case on active polymeric substances with different compositions. A short discussion with exchange of opinions and possible solutions took place but no concrete decision was taken. Industry was advised to stay in close contact with the future possible eCA and provide more specific proposals for an application for the approval of the active substance(s) which can be discussed at the other working groups and policy level too.

8.3 Redefinition of active substance according to Article 13 of Commission Delegated Regulation (EU) No 1062/2014

The chair explained the problems (different names for classification and labelling, delay in the approval process) occurring when a redefinition of an active substance is delayed to the peer review period. Therefore the working group members agreed on the following procedure:

1. The eCA and applicant discuss and agree on the redefinition of the substance.
2. The eCA initiate an early working group discussion (APCP) for the redefinition.
3. The applicant is invited to the early WG discussion.
4. During the early working group discussion, member states, applicant and ECHA can exchange their views and agree/disagree on the redefinition of the active substance.
5. In case of disagreement, the active substance is not redefined.
6. In case of agreement, the eCA informs officially ECHA about the redefinition after the working group meeting.
7. ECHA updates the Registry.
8. ECHA publishes the invitation to take over the role of participant.

8.4 Details and extent of quality control data

The working group agreed on the criteria below which should not be regarded as fixed and compulsive. Therefore the criteria will not be included in the Technical Agreements for Biocides (TAB).

- Period of monitoring/age of the data: not older than 5 years.
- Frequency of monitoring and data points: all batches of the time period which can be summarised with the maximum and minimum of the measured values, however with the possibility to request all (raw) data.
- What should be monitored: minimum purity and the content of the relevant impurities; in case this information is not measured and therefore not available, a new 5-batch analysis might be requested form the applicant.
- Outliers: outliers should be considered carefully on a case-by-case basis; blending might be possible.
- Quality system: in-house methods or general production methods are acceptable, hence not fully validate and specific.

9. Any other Business (AoB)

9.1 Union authorisation

ECHA provided a presentation on the process and progress of union authorisation. WG members were encouraged provide items which might be critical for this process. A brief brain storming outlined possible problems and the need of further elaboration.

9.2 Lessons learnt

The chair reminded the working group members to keep the deadlines highlighted the different process flows.

9.3 Additional items

- **Residues in food and feed and MRL settings**

  This issue will be followed up via e-consultation.

- **Number of reference sources and specifications are eligible**

  The chair clarified that the eCA can include as many (reference) sources as complying with the reference specification. However, these sources must be included in the CAR for approval of the active substance. All sources which are not included in the CAR but used for biocidal products must apply for the assessment for technical equivalence to ECHA before they can be used for product authorisation.

- **Precursors of in situ generated active substances – reference source**

  The chair clarified that in general the reference specification will be set on the composition of the precursor(s). Hence, no 5-batch analysis of the in situ generated active substance is needed.

Minutes of Human Health WG

WG-III-2016 (24-26 May 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 20 participants present, of which five were core members and two alternate core members. One stakeholder observer was present for the non-confidential agenda items. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

New procedure is now in place for nomination of members; from 16 May onwards the Director of the eCA is responsible for nominating the WG members.

There is a new option for signing in to ECAS to replace pin code received by sms.

The members were reminded that R4BP 3 should be used for communication between applicants and eCAs; the 'Submissions' folder in S-CIRCABC can be used only as a back-up until September 2016.

In addition, the Data Protection Officer from the ECHA Executive Office gave a brief presentation of the Conflict of Interest matters.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. No additional items to the agenda were proposed. The agenda was agreed without changes.

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

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

5. Agreement of the draft minutes from WG-I-2016

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Azamethiphos (eCA UK) PT 18

There are two open points that will be closed in an ad hoc follow-up. These concern the genotoxicity studies with possible implications on reference values, and the risk assessment for the ready-to-use product, which was considered incomplete. The remaining open points were closed.

6.2 Margosa extract (eCA DE) PT 19

The WG mainly discussed the toxicological reference values and concluded that only a systemic risk characterisation is necessary. Changes were also agreed in the exposure assessment and risk characterisation. All points were closed.

6.3 Silicium dioxide (Silicium dioxide/Kieselguhr) (eCA FR) PT 18

There were three open points that will be closed in an ad hoc follow-up. These concern the effects of long-term inhalation exposure and the related issues of determining the acceptable exposure concentration for inhalation and the acceptability of read-across between different types of amorphous silica.

6.4 Silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) (eCA FR) PT 18

A discussion took place on the principles for assessing nanomaterials as biocides. The conclusions of this discussions were limited. All points were closed except for one concerning the acceptable exposure concentration for inhalation.

6.5 Dichlofluanid (eCA UK) PT 21

The main discussion points concerned toxicological reference values and exposure assessment. All points were closed.

6.6 OIT (eCA UK) PT 8

There was discussion on toxicological reference values, dermal absorption and the assessment of inhalation exposure. All points were closed.

6.7 PHMB (1600;1.8) (eCA FR) PT 5

Exposure of livestock and the possibly following consumer exposure were discussed. Risk assessment of animals was also considered, as well as the extent of dermal absorption. All points were closed.

6.8 Sodium hypochlorite, Calcium hypochlorite, Chlorine (eCA IT) – reference values and dermal absorption

The discussion concerned the setting of reference values and dermal absorption values. The acceptable daily intake and acute reference dose were agreed, while it was concluded that no systemic acceptable exposure levels are necessary as the effects were considered local rather than systemic. The WG also agreed on the relevant values to be used in the local risk characterisation.

7. Technical and guidance related issues

7.1 Update on guidance development

SECR informed that the Partner Expert Group (PEG) meeting for the first revision of guidance volume V on active micro-organisms was held on 27 April 2016. Following a four-week commenting period, the guidance is expected to be published during summer 2016.

The consultation on the draft guidance on disinfectant by-products will be launched in Q3 2016 and the publication target is in November/December 2016.

7.2 Update on Ad hoc Working Group – Human Exposure (HEAdhoc)

SECR informed that the nine recommendations agreed so far by the Working group are publicly available on the ECHA website.

SECR gave an update on the outcome of the HEAdhoc-1-2016 meeting which took place in Berlin on 28 and 29 April, hosted by BfR.

The recommendations foreseen to be prepared in 2016 include:

- Scenarios for teat disinfection (PT3): the recommendation will be developed based on the models proposed by NL. The recommendation is planned to be agreed at the WG-IV-2016.
- Transfer coefficient for ConsExpo rubbing-off model: a recommendation will be drafted, reflecting the discussions during the HEAdhoc-1-2016 meeting.

7.2(a) Recommendation "The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling"

The recommendation was agreed by the WG.

7.2(b) Recommendation "Product application amount for repellents – exposure assessment"

The recommendation was agreed by the WG with modifications.

7.3 Update on Ad hoc Working Group- Assessment of residue transfer to food

SECR presented the document WGIII2016_TOX_7-3 for discussion and agreement.

The document outlined the status of the ARTFood guidance and defined an approach to assess exposure to biocidal active substance residues in food and feed in the absence of agreed guidance. The WG members highlighted that, postponing the dietary risk assessment to product authorisation would not solve the lack of guidance on dietary risk assessment, especially if the estimation according to the draft guidance would show a risk for the consumers. Moreover, the need of a clear guidance on dietary risk assessment has been raised to have a harmonised approach through the European countries. It has been proposed to publish the draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Product with the aim of providing the eCAs and applicants the methods for the estimation of livestock animal exposure. The publication of the draft would allow the interested parties to apply the exposure methods and to collect experience and feedback that might be implemented in the final version of the guidance. SECR acknowledged the lack of agreed guidance on biocidal active substance residues in food and feed and proposed the approach as presented in the document. SECR invited the WG members to contact the relative CA representatives to raise the concerns expressed during the WG also at the CA meeting, where a policy discussion on MRL setting for biocide is ongoing.

The WG agreed on the approach proposed in the document WGIII2016_TOX_7-3. Briefly, the following interim principles will be used as long as there is no agreed guidance:

a) A preliminary assessment of the transfer of biocidal active substance residue into food and feed should be included as an annex to the CAR, clearly indicating that the assessment has been performed according to non–agreed guidance and it is an eCA proposal.

b) A preliminary dietary risk assessment might be performed if relevant and possible. The assessment should be included as an annex to the CAR as described above.

c) The following provision would be included in section 2.4 of the BPC opinion on a case by case basis: “An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs”.

As long as there is no agreed guidance, the conclusion on dietary risk assessment will not affect the approval of the active substance.

If it is concluded that evaluation is not possible using the information available in the dossier, it may be necessary to postpone the exposure estimation to residue and the dietary risk assessment to product authorisation stage.

7.4 Risk assessment of corrosive substances

SECR presented the meeting document WGIII2016_TOX_7-4 which contained proposals for agreement. The following entries were agreed and will be included in the Technical Agreements for Biocides (TAB):

1. **For active substance approval, is systemic risk characterisation necessary for corrosive concentrations?**

   Dermal and oral routes. The use of appropriate personal protective equipment (PPE) and risk mitigation measures (RMM) will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations.

   It should be mentioned in the CAR that for corrosive concentrations the systemic risks are covered by the local risk characterisation.

   Inhalation route. If inhalation exposure is possible following the use of a corrosive concentration of the active substance, systemic risk characterisation should be performed, independently of whether or not the substance is corrosive as inhaled.

2. **How should corrosivity be estimated for formulations that have not been tested?**

   For formulations that have not been tested, bridging principles and the calculation method should be applied where relevant in estimating corrosivity. For the calculation method, specific or generic concentration limits should be applied.

3. **How should dermal absorption values be derived for corrosive concentrations of the active substance?**

   A default dermal absorption of 100 % should be indicated for corrosive concentrations unless there is data indicating lower dermal absorption. This value would normally not be used in the risk assessment because dermal exposure should be avoided using RMM.

7.5 Criteria/checklist for ECHA accordance check

SECR presented the meeting document WGIII2016_TOX_7-5 describing the draft checklist that ECHA will use in performing accordance checks to Competent Authority Reports (CARs) submitted by evaluating Competent Authorities.

There were no major comments to the checklist but SECR informed that comments and suggestions on the checklist can be submitted to SECR at any time, noting that the checklist is already in use and will be applied in accordance checks.

7.6 Principles for reopening TM/WG agreements

SECR presented the meeting document WGIII2016_TOX_7-6 which was to agree on the principles to be applied in deciding whether an earlier agreement should be reopened or not.

The WG overall agreed on the document but SECR will provide a revised version before final agreement. The principles were already considered applicable during WG-III-2016.

Briefly, a discussion should normally not be reopened unless additional information or new guidance or methodology has become available, or new reference values are needed for a new PT, or where a clear error is identified.

8. Any other business

8.1 Union authorisation

SECR informed on the meeting document WGIII2016_TOX_8-1 which highlights expected discussions and issues concerning Union Authorisations that may be raised during the WGs and BPC. The aim of the document is also to more specifically define the expertise of the WGs and the BPC. Input on the document can be provided in a dedicated S-CIRCABC newsgroup until 8 July 2016.

8.2 Other information & lessons learned

SECR informed that a new ad hoc Working Group (WG) is expected to be formed for micro-organisms. The mandate for this WG will be discussed in BPC-16 in June 2016. The scope is foreseen to cover the approval, renewal and review of biocides containing micro-organisms (microbial active substances), as well as guidance and other issues related to active micro-organisms. The WG would be expected to be established in autumn 2016.

A workshop was organised on 19 May in Berlin on the assessment of dermal absorption for antifouling products and other matrices that form a dry film during testing. Several proposals were discussed on how dermal absorption testing (new or existing studies) and read-across between products should be handled. A workshop report will be prepared, and SECR will provide a document for discussion at WG-IV-2016.

Minutes of Efficacy WG

WG-III-2016 (25-26 May 2016)

1. Welcome and apologies

The Chair welcomed all participants to the 12th Efficacy WG meeting. There were eight core members who participated in the meeting. In addition, seven flexible members and one ASO representative participated to the EFF WG meeting.

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

2. Administrative issues

ECHA gave a brief summary on the administrative issues, and in addition a presentation concerning conflicts of interest was given.

3. Agreement of the agenda

The Chair introduced the agenda items, one additional agenda item concerning disinfectants claims discussed at CG level was added by SE under AOB.

Conclusions and actions

Members agreed on the proposed agenda.

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

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

5. Agreement of the draft minutes from WG-I-2016 and WG-II-2016

An open question of whether it had been agreed on resistance label claims that "…such claims could be made on a case by case basis…" remained for WG-I-2016 minutes. ECHA confirmed that based on the recordings of the meeting, the conclusion was not clear. The sentence was removed from the minutes of WG-I-2016, and the amended minutes were agreed by the EFF WG.

The Chair informed that comments for the minutes of WG-II-2015 had been received from FR and SE concerning some editorial corrections already accepted, as well as agenda items "6.7. Status of ongoing ad-hoc follow up of silver zinc zeolite" and "7.1.a Appendices for PT1-5". With reference to point 6.7., the comments were accepted. The question for 7.1.a was whether the column "Target site" was agreed to be removed from PT1 only, or also from PT:s 2-4. After reviewing the tables the EFF WG decided not to remove the Target site column from any PT, but to update its content concerning PT 1. In addition the word "classification" referring to PTs was changed into "approach". The minutes with these amendments were agreed by the EFF WG.

Concerning a question from SE and NL, ECHA informed that comments for the minutes can always be found from S-CIRCABC Newsgroups under the relevant title, whereas the draft, updated and final minutes are uploaded under the next WG meeting in the Library.

6. Discussion of active substances[1]

6.1 Azamethiphos (eCA UK)

There were no open points concerning efficacy for discussion in the RCOM table, so the discussion table was only provided to record the agreement/disagreement of the WG.

The EFF WG agreed on the evaluation of the eCA.

6.2 Dichlofluanid (eCA UK)

There was one remaining open point concerning efficacy for discussion. The EFF WG agreed that additional information of efficacy tests will be added to Doc I of the CAR. The point was closed, and the EFF WG agreed on the evaluation of the CA.

6.3 Margosa extract (eCA DE)

There were seven remaining open points concerning efficacy. The EFF WG agreed that the description of the intended effect of the active substance in the CAR should be rephrased in accordance with the proposal from EL (point 1). It was also concluded regarding the reference product that the innate activity of the active substance has been sufficiently proven, and additional tests should be submitted at product authorisation stage (points 2 and 5). Regarding the described use scenario the EFF WG concluded that the CAR should be rephrased to highlight that it is probably not a realistic one (point 3). A more detailed description of results was not considered necessary (point 6), and the explanation of eCA on the use of heat homogenisation (point 7) was considered sufficient.

Regarding specification of the extract used in efficacy tests the EFF WG agreed that the eCA will ask the applicant to provide more detailed information, or at least a statement that the extract used in efficacy tests matches the technical specification. This point (point 4) was left open, and an ad hoc follow-up will be launched.

6.4 Silicium dioxide (eCA FR)

There were no open points concerning efficacy for discussion in the RCOM table, so the discussion table was only provided to record the agreement/disagreement of the WG.

The EFF WG agreed on the evaluation of the eCA.

6.5 OIT (eCA UK)

There were two remaining open points concerning efficacy. The EFF WG concluded that the efficacious dose should be expressed as a concentration of the working solution and retention of product in wood. The retention rate is given in the ecotoxicology part, and reference to it should be made in the efficacy part. In addition, the criteria given in the NWPC standard as well as their fulfilment should be added. With these amendments the point was closed.

Regarding vacuum pressure impregnation the EFF WG agreed that the applicant will be given the opportunity to provide information that the dose used in the risk assessment is relevant. Otherwise it should be clearly stated in the CAR that the application rate used for this mode of application is not supported by efficacy data. This point was left open, and an ad hoc follow-up will be launched.

6.6 PHMB (eCA FR)

There were no open points concerning efficacy for discussion in the RCOM table, so the discussion table was only provided to record the agreement/disagreement of the WG.

The EFF WG agreed on the evaluation of the eCA.

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

6.7 Status of ongoing ad hoc follow-ups

6.7.a Silver zinc zeolite (eCA SE)

SE presented the current status of the silver zinc zeolite and informed that the Applicant has not provided the required data on PT 7 and PT 9. It was agreed that SE will contact the Applicant via R4BP to confirm that the active substance is not supported for PT 7 and PT 9.

6.7.b Sodium hypochlorite (eCA IT)

All points had been closed in the ad hoc follow up.

6.7.c Calcium hypochlorite (eCA IT)

All points had been closed in the ad hoc follow up.

6.7.d Chlorine

All points had been closed in the Ad hoc follow up.

7. Guidance

7.1 Volume II Efficacy – Part B + C: chapter 5.5. - Preservatives

SE presented the current status of the Chapter and the comments received were discussed by the EFF WG. It was agreed that a table including examples of the most common uses, test methods, relevant organisms, representative materials and acceptance criteria will be added. SE will prepare a draft template and Cefic will provide some input from the Preservatives WG before the forthcoming PEG.

Placing and testing malodour claims was discussed as well. IE informed about existing CEN standard for testing malodour (EN13725). It was agreed to include an example related to consortium of bacteria preventing malodour as a footnote to the guidance. A sentence stating that in case of biocides the prevention of malodour has to be achieved by the prevention/killing malodour causing microorganisms will be added as well.

NL informed of a publication concerning malodour producing bacteria, and offered to provide further information on testing malodour producing micro-organisms.

With reference to appendices A and B SE will correct the headings of Appendices A and B for Chapters 5.3. and 5.5. and will formulate a brief description for both of them. The new document “Categorisation of use” (Item 8.7. in the agenda) drafted by SE was briefly introduced and it was agreed that the EFF WG members will comment on it by the end of June. FR pointed out that conformity of terms and contents with other guidance (e.g. PT 8) has to be verified.

Restructuring and other agreed amendments to Chapter 5.5. will be implemented by SE. Chapter 5.5. and appendices will be circulated for checking within 10 days by the EFF WG members.

7.2. Efficacy testing of Treated Articles – (health) claim matrix

The discussion focused on specific claims, i.e. hypoallergenic, antiallergenic and preventing infections. The EFF WG opinion was that they are correct claims, but some of the members did not consider them as biocidal claims. The EFF WG finally agreed to remove these specific claims, and to add a footnote explaining that other claims than killing or preventing growth are in principle possible, but they have to be discussed with the Competent Authorities, and they might require tier 3 testing. FR suggested to add minimum spectrum of activity for health care, in order to be consistent with the products claim matrix in PT 2 guidance. NL pointed out that there is no consistency in required log reductions either, and these products are probably not sufficiently efficacious to kill yeasts, therefore it would be unrealistic to add yesticidal activity here. In addition for PT2 we have bactericidal and yesticidal activity claimed only for hospitals and not for other areas.The EFF WG decided

not to add yeasts to the minimum spectrum of activity in the claim matrix for treated articles intended to be used in health care.

7.3 SPC editor in relation to target organisms

Comments for lists of Common names and Scientific names had been received from EL, FI and NL. The EFF WG concluded that the revision of these lists requires more time than available at the WG meeting. A tree-like structure for the names was proposed by DE and supported by SE. The Chair informed that this is work for the future, since the lists have to be ready by the end of June, in order to be included in the next SPC release in September 2016. The EFF WG agreed that ECHA will draft a table combining common and scientific names and including all proposals received. The EFF WG members were invited to check the correctness of all names and their relevance in relation to information given in the SPC. The work was divided between the members as follows: PT 1-5 - NL; PT 8 - FR; PT 14 - DE; PT 18+19 – EL; preservatives – SE; the rest - HR.

8. AOB

8.1 Teat disinfection – proposal for agreed parameters to be used in the Phase 2, step 2 synthetic skin test (closed session)

The Iodine Registration Group (IRG) PT3 sub-group had sent a statement paper including criteria for Phase2/step 2 efficacy testing of teat disinfectants for approval by the EFF WG. NL shared experiences of the iodine applications for authorisation received by them, which contained some variable and non-consistent results.

Regarding the statement paper the EFF WG concluded that:

- contact time
  - pre-milking disinfection: 30 seconds or less and should not exceed 60 seconds
  - post-milking: normally 1 minute but should not exceed 5 minutes

The above mentioned contact times are in line with the PT1-5 efficacy guidance, deviations from these requirements must be justified in the application for authorisation and will be evaluated on a case-by-case basis.

- soiling conditions for post-milking disinfection: 10g/L skimmed milk, as specified in EN 1656
- soiling conditions for pre-milking disinfection: 10g/L BSA + 10g/L yeast extract, specified as high level soiling in EN1656
- application protocol and type of the synthetic skin are to be decided by the applicant
- only one reference bacteria to be tested in 2,2 tests (reference EN 1656 clause 5.8.3), worst case from phase 2 step 1 test – it is temporarily accepted when adapting to the new test methodology, however relevant justification should be given.

Some members informed also about different practices in their countries: in UK teat disinfectants with virucidal claim directly applied on animal skin fall into veterinary medicine legislation. In NL they are considered as biocides as long as they are applied on intact animal skin.

8.2 Criteria for accordance check of the CAR – evaluation of active substances

This agenda item was skipped due to time limitations and will possibly be discussed in WG-IV-2016 in September.

8.3 Permethrin containing biocidal products used for treatment of textiles - testing requirements (closed session)

The applicant presented the background, test results and asked the EFF WG which tests can be accepted as laboratory tests, simulated use-tests, and field tests. The eCA pointed out that in the application in question the mode of action of permethrin is to reduce bites, and the effect is neither directly insecticidal (PT 18) nor repellent (PT 19), and it is difficult to decide at which level the killing effect should be accepted.

It was decided that this type of effect can be considered PT18, and not PT19, because there is no effect without contact, so it cannot be seen as a repellent. The claim should be in line with PT18: contact insecticide, prevents biting of mosquitoes and ticks.

The existing guidance does not give any valuable advice how the criteria for acceptance should be derived. The EFF WG concluded that the WHO tube/cone test can be regarded as a laboratory test, and the arm-in-cage test (as described in the PT19 guidance) as a simulated-use test. As a field test the publicly available studies presented by the applicant may be submitted, a read across is possible as the concentration of the active substance used in them is the same as for the application in question.

8.4 Cooperation between ECHA and CEN

The Chair informed that ECHA does not support CEN members to participate in the Efficacy WG meetings, since the main scope of the meetings is on active substance evaluations and biocidal product authorisations and for such cases CEN is not an interested party. Moreover the number of WG members should be somehow limited to enable efficient discussion on the main topics. Cooperation and partnership of ECHA and CEN should be initiated from a different level than the EFF Working Group. ECHA will send the information to CEN.

8.5 Union authorisation

This agenda item was skipped due to time limitations. ECHA will circulate the document to the EFF WG for commenting.

8.6 Other information & lessons learned

ECHA informed that concerning PT 5 efficacy guidance a list of open points for discussion will be sent after the EFF WG meeting for commenting, and will be discussed in a virtual meeting 20 June 2016.

A request from ECHA was made to the EFF WG members to inform what kind of information/studies have been submitted for anticoagulants containing products in PT 14. Discussion of how applications for major changes in this group should be assessed in a harmonised way will take place in EFF WG-IV-2016 in September.

Information of forthcoming ad hoc WG Micro-organisms, with scope on biocides containing micro-organisms as active substances, was given. ECHA also informed of the EFF WG conclusions made on ad hoc follow-ups on Aircraft disinfection, Treatment against *Serpula lacrymans,* and Tests against enveloped viruses.

In addition, an overview of the status of Efficacy guidance Volume II Parts B + C (assessment and evaluation) was given. The Chair informed that revision of PT 18 and PT 19 guidance is foreseen end of 2016 / beginning of 2017. FR informed that work on PTs 11 and 12 has started together with the industry, and some further information of the status of this guidance development may be given in September.

The Chair requested eCAs to respect the deadlines given by ECHA for submitting RCOM and updated RCOM, to combine different PTs in one table, and to indicate clearly whether the point is open or closed. As regards to the question from WG-II-2016 of label claims for disinfectants to be included in the SPC, the Coordination Group had decided in their 17th meeting to refer to the Commission to prepare a proposal on the regulatory aspects. The Chair also informed that any issues to discuss during AOB agenda item for WG-IV-2016 have to be submitted by 1 September 2016.

Minutes of Environment WG

WG-III-2016 (30-31 May 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 17 participants present, of which six were core members and nine flexible members. In addition two rapporteurs where present in the meeting. No representatives from accredited stakeholder organisations were present. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

New procedure is now in place for nomination of members; from 16 May onwards the Director of the eCA is responsible for nominating the WG members.

There is a new option for signing in to ECAS to replace pin code received by sms.

The members were reminded that R4BP 3 should be used for communication between applicants and eCAs; the 'Submissions' folder in S-CIRCABC can be used only as a back-up until September 2016.

In addition, the Data Protection Officer from the ECHA Executive Office gave a brief presentation of the Conflict of Interest matters.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. No additional items were proposed. The Chair further indicated that the substance PHMB will be discussed before Dichlofluanid and that items 7 and 8 of the agenda will be handled in a flexible way. 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 were declared.

The Deputy Chair a conflict of interest with one active substance. Therefore the Chair will chair the sessions of the respective active substances.

5. Agreement of the draft minutes from WG-II-2016

The minutes were agreed without further changes.

Concerning a comment of UK on the sequence of guidance concerning Vol IV Part B compared to the TAB, SECR explained that the latest status is reflected in the TAB.

6. Discussion of active substances[2]

6.1 Azamethiphos (eCA UK) – PT 18

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee. The list of required information before product authorisation prepared by the eCA and agreed by the WG should be added to section 2.5 of the opinion.

Action SECR: to include an entry to the TAB concerning soil (release via manure) that run-off to surface water and leaching to groundwater in PT 18 are generally considered as continuous release, unless the criteria for intermitted release as provided in Vol. IV Part B are fulfilled.

6.2 Silicon dioxide Kieselguhr (eCA FR) - PT 18

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

6.3 Amorphous surface silicon dioxide (eCA FR) - PT 18

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

6.4 Dichlofluanid (eCA UK) – PT 21

There are two open points that will be closed in an ad hoc follow-up. These concern the endpoint for algae and the approach on how to take into account multiple applications to calculate the PECsoil.

Action eCA: to prepare the *ad hoc* follow up in collaboration with SECR. eCA to update the CAR based on the outcome of the *ad hoc* follow up accordingly.
In addition, **UK** to take up the DT50 for MAMPEC (use of the highest DT50 value for the risk assessment instead of the geomean if three or less than three DT 50 values are available) in the manual for product authorisation for PT 21.
Action SECR: Revise the existing TAB entry 19 to make it clear that an evaluation on if an aggregated exposure assessment is needed should be always performed (not only for PT 6) based on the decision tree provided in the CAR template.

6.5 PHMB (eCA FR) – PT 5

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

6.6 Margosa extract (eCA DE) – PT 19

There are two open points that will be closed in an ad hoc follow-up. These concern the PBT assessment of the active substance and a refinement of the exposure assessment post-WG meeting, which needs confirmation by the WG.

Action eCA: to prepare the *ad hoc* follow up in collaboration with SECR. eCA to update the CAR based on the outcome of the *ad hoc* follow up accordingly.
Action SECR: to add an entry to the TAB; as default length for barrier treatments against ants in PT 18 and 19 (door steps and windows) a value of 10 m was agreed. The width of

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

the barrier will be kept flexible and should be defined case by case depending on the application technique. When in the future further data on specific cases have been collected with regard to the application techniques and typical width of the treatment area, fixed default values can be defined.

6.7 OIT (eCA UK) – PT 8

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee. The list of required information before product authorisation prepared by the eCA and agreed by the WG should be added to section 2.5 of the opinion.

Action SECR:

- To clarify if wood treated with a short term antisapstain still falls under the BPR. If yes, a consultation of the AHEE will be initiated by SECR on how to assess such short term antisapstain treatments (exposure assessment).
- To include a TAB entry on the flow rate of a creek for calculation of $PEC_{surface\ waters}$/industrial storage. The WG agreed to use for consistency reasons with regard to previous assessments of PT 8 substances the value of 0.3 m3/s).
- To include a TAB entry on the need of an STP assessment in case of a bunded storage place. The WG confirmed that no exposure assessment for the STP is needed, provided that the standard RMM for PT 8 is applied ("... and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal").

6.8 Status of ongoing Ad hoc follow-ups (ECHA)

The item was not presented at the WG meeting but an overview was uploaded to the meeting folder in the confidential S-CIRCABC section.

7. Technical and guidance related issues

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

SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. Updates from WG members during the meeting have been included after the WG meeting (see updated table in Appendix 2 below).

7.2 Feedback from AHEE-1 (ECHA)

SECR provided feedback on AHEE-1, where the following documents have been discussed (numeration refers to the agenda item of AHEE-1):

5.2 Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments (DE)

5.3 Application of SimpleTreat version 4.0 instead of current version 3.1 for the environmental exposure assessment of biocides (DE)

5.4 How to use market share data in order to derive a market penetration factor (Fpen) different from default values? (ECHA)

5.6 PT 8: Should the city scenario be used and replace current scenarios in the OECD ESD for PT 8? (NL)

5.7 PT 18: Taking into account degradation in manure (NL)

5.8 Items for clarification resulting from the ESD Excel sheet preparation (ECHA)

5.9 Proposal on exposure assessment of metabolites in the terrestrial compartment (DE)

6.1 Draft guide on PT 21 product authorisation (UK, NL)

The overall aim is to adopt these documents at WG-IV-2016. In addition an overview was provided on the specific follow-ups including proposed timelines.

8. AOB

8.1 Union authorisation

SECR informed on the meeting document WGIII2016_ENV_8-1 which highlights expected discussions and issues concerning Union Authorisations that may be raised during the WGs and BPC. The aim of the document is also to more specifically define the expertise of the WGs and the BPC. Input on the document can be provided in a dedicated S-CIRCABC newsgroup until 8 July 2016.

8.2 Other information & lessons learned

SECR informed on the following issues:

- Extended accordance check (ENV): It was prepared in the frame of back log project following discussions at active substance workshop in April 2015, eCAs are invited to fill in the extended accordance check and submit it together with the CAR (as a "transparence tool" on what SECR would expect in the frame of the accordance check). SECR will specifically check information noted in the fields "Most relevant", since they are mandatory: if no information/justification provided in these fields, the accordance check will fail.

  WG members asked from when the extended accordance check should be used, SECR responded that it should be used for all CARs to be submitted for the next submission window after the WG meeting (process flow 16).

- Analysis of the relevance and adequateness of using Fish Embryo Acute Toxicity test (FET) Test Guideline (OECD 236) to fulfil the information requirements and addressing concerns under REACH: the outcome of this analysis constitutes a basis to understand how currently the FET test might be used in the regulatory context of REACH (http://echa.europa.eu/web/guest/publications/technical-scientific-reports).

- A new ad hoc Working Group (WG) is expected to be formed for micro-organisms: the mandate for this WG will be discussed in BPC-16 in June 2016. The scope is foreseen to cover the approval, renewal and review of biocides containing micro-organisms (microbial active substances), as well as guidance and other issues related to active micro-organisms. The WG would be expected to be established in autumn 2016.

With regard to lessons learned, eCAs and MS were invited to respect the deadlines since all delays cause problems to others. Most critical in SECRs point of view are the updated RCOM, disagreement on closing a point in the updated RCOM, closing points (only commenting MS can close points – actively provide feedback (MS)/ ask for feedback (eCA)) and clearly indicate if a point is open or closed in the updated RCOM.

In addition, it was noted that the conclusions uploaded after WG meeting are only provided for information, not for commenting. Comments on the draft minutes should be provided in the dedicated Newsgroup (link sent by SECR after upload of draft minutes) and not via email.

In case of questions on organisational details, related functional mailbox BPC-WGs@echa.europa.eu should be always included in any email.

One WG member noted that the TAB is difficult to be found on the ECHA webpage, SECR responded that a link to it on the ESD specific webpage is currently under preparation.

Appendices:

Appendix 1:

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

Note:

- Issues unchanged since the previous WG meeting are highlighted in grey shading.
- Closed issues are ~~stroke through~~.

1. Guidance related documents

No.	Title (current leader)	Status
1.1	Scenario for freshwater marinas (**NL**) / PT 21 PA manual (**UK**)	Intention for scenario preparation presented at TM IV 2013. NL has started discussion with IND and has received information from industry. NL has compiled the reactions from the e-consultation on PT 21. **Outcome was included in the PT 21 PA manual discussed at AHEE-1. Endorsement scheduled for WG-IV-2016.**
1.2	Leaching to groundwater from paint, coatings and plaster (**NL**)	The document was discussed at WG-II-2015. NL agreed to make some clarifications in the document for better readability. The document was distributed for commenting after WG-II-2015, no comments have been received (commenting period ended on 8/5/2015). DE commented directly to NL during the physical meeting. **The document will be updated and NL will explain the method in more detail**.
1.3	Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments (**DE**)	Discussed at WG-II-2014: two remaining open issues have been identified: a) the application date for manure application on grassland as well as b) the application method and soil depth for manure application on grassland (5 cm incorporation or surface application). **Discussion at AHEE-1, endorsement scheduled for WG-IV-2016.**
1.4	Evaluation of the model SimpleTreat (**DE**)	DE did not yet receive the final report and the announced manual for the new SimpleTreat version. DE is currently clarifying some open points with the provider of the tool; the final report will be provided to WG members as soon as these are solved. A document was provided for information at WG-I-2016.

No.	Title (current leader)	Status
		Discussion at AHEE-1, endorsement scheduled for WG-IV-2016.
1.5	Environment Substances of Concern (SoC) (**DE / DK**)	At WG-III-2014 it was concluded that further guidance to cover the environmental part should be continued to be developed. DE prepared a proposal based on the work done so far by UK and included comments from the former SoC-WG which was send to DK for a first commenting. DE included comments from DK into the guidance. **The final document was provided by DE on 12 May 2016. Items to be clarified by SECR. Endorsement by written procedure.**
1.6	2nd EU Leaching Workshop for PT 8 (**ECHA**)	The points that were agreed so far at the workshop and at subsequent TM/WG meetings have been included as embedded document in the TAB. The outcome of the **e-consultation on protection goals** was discussed at WG-III-2015. Item was closed at WG-III-2015; it can be re-opened following a request from the BPC/CA meeting. **Item was send to BPC-15 requesting feedback on two open items:** The BPC recommended that (1) the **definition of protection goals for PT8** will not be taken up now and the exposure and risk assessment methods as currently applied are acceptable. First an impact assessment is needed for (2) the **re-definition of the TIME scheme** (TIME1 = 30 d, TIME2 = 365 d, TIME 3 = service life). An agreement was reached how to perform the impact assessment. Based on data collected from MSs, SECR will perform an impact assessment for the risk assessment at the new TIME2. ***Members*:** Start to perform a risk assessment for the new TIME2 (= 365 d), however not using it for decision making. Send the risk assessment to SECR via CIRCABC. ***SECR*:** to open a Newsgroup on CIRCABC. To collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year). **SECR** to include additional time also in the Excel sheet for PT 8 currently under preparation.
1.8	Fish net scenario (**ECHA**): discussion on the usefulness of the new version of MAMPEC to be initiated	Discussion was started by NO. **Possible inclusion in MAMPEC discussed with Deltares at AHEE-1, funding to be clarified by SECR**.
1.9	1st revision of Vol. IV Part B (active substance) (**ECHA**)	1st revision: definition of subjects for first revision and assignment of volunteers taking over the subjects were agreed at WG-I-2016. **Reminder: Draft text to be provided by 15 June 2016.**
1.10	Guidance on aggregated exposure assessment (**DE**)	The discussion of the draft guidance is re-scheduled for an electronic procedure, **to be started in Q2 / Q3 2016**.

No.	Title (current leader)	Status
1.11	TAB (**ECHA**): Technical Agreements on Biocides	The first version of the TAB (ENV+HH combined) was uploaded to the ECHA webpage; embedded documents have been changed into links and can now be opened. The first revision was uploaded for commenting after WG-I-2016. **Comments have been included by SECR (GW item to be clarified at WG-IV-2016), TAB v1.1 will be uploaded within the next 1-2 weeks.**
1.13	ESD for PT 6 (**DE**)	Distributed for commenting on 07 July 2015, deadline for commenting was 31 August 2015. ESD was discussed at WG-V-2015. Commenting of closed points in the RCOM table until 16 December 2015. **Comments to be included in the ESD by DE.**
1.14	Leaching tests for PT 7, 9 and 10 (BAM)	Protocols have been discussed at WG-IV-2015. The final versions have been uploaded by DE in the dedicated S-CIRCABC Newsgroup. **The protocols have been included in TAB v1.1.**
1.16	Guidance on disinfectant by-products (Dedicated WG)	The guidance was uploaded to S-CIRCABC. There is no official commenting period, but any written input can be sent by 20 January 2016 to the following functional mailboxes bpc-environmentalexposure@echa.europa.eu and biocides-bpc-active-substance@echa.europa.eu **The PEG meeting was postponed (further information under item 8.2).**
1.17	Guidance on free radicals (NL)	For information: Workshop took place in February 2016. **Further actions?**
1.18	Evaluation of ESD PT 14	Shortcomings of the current emission scenario document for rodenticides (ESD PT14) became obvious within the national product authorisation of rodenticides. UBA Germany has initiated a research project to review the described scenarios and assumptions. The project is scheduled from January 2016 to November 2017. **As one of the first steps an e-consultation has been initiated on the current praxis of rodent control in the EU.**

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

No.	Title (current leader)	Status
2.1	1. PT 6.1/ detergents/ Consumption based approach: amount of disinfectant for laundry The value to be used for the amount of disinfectant per kg of dirty laundry need to be harmonised 2. PT 6/ Harmonisation of the daily emission from fabric washing (TGD IV value vs HERA value)	Outcome of the e-consultation was discussed at WG-IV-2015. Some open points were taken up in the frame of the ESD for PT6. **The outcome of the consultation will be reflected in the ESD for PT 6.**
2.2	PT 6.3 / Pulp and paper processing fluids / Consumption based approach: use of 50% market share ⇒ *WG-II-2014 – item 6.4*	To be followed up under point 2.5.
2.3	Use scenarios for PT 9 roof membranes (prepared by DE): Discussion on if the correction of the equations provided in the (revised) OECD ESD for PT8 is also applicable for this guidance document ⇒ *WG-III-2014 – item 7.4*	Taken up by DE and NL (in the frame of the meeting related to item 2.5) **Conclusions to be provided for agreement to the WG.**
2.5	How to use market share data in order to derive a market penetration factor different from default values? ⇒ *WG-I-2015 – item 6.2* + *WG-II-2015 – item 7.3*	AHEE consultation ended on 28 August 2015. Based on the comments received the proposal will be revised and then re-commented/confirmed by AHEE. A discussion on two items took place at WG-IV-2015. **Discussion at AHEE-1, endorsement of revised recommendation scheduled for WG-IV-2016.**
2.6	PT 6.3/ Default value and application of Fbroke (currently 0.2) + correctness of the equation provided in the ESD ⇒ *WG-I-2015 – item 7.1*	Outcome of the e-consultation was discussed at WG-IV-2015. One item will be taken up in the frame of the ESD for PT 6. **The outcome of the consultation will be reflected in the ESD for PT 6.**
2.7	PT 18: How to derive values for the cleaning efficiency FCE (=> Release and exposure estimation of the biocidal product during cleaning step) ⇒ *WG-III-2015 – item 6.4*	AHEE member to take over item to be assigned.
2.8	PT 2, 3, 4: Preparation of specific scenarios for RTU - small scale applications ⇒ *WG-III-2015 – item 7.3*	ECHA contracted out the preparation of scenarios, no proposal available yet.
2.9	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application	AHEE member to take over item to be assigned.

No.	Title (current leader)	Status
	rate per surface (leaching rate assuming 100% leaching) or use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8). ⇒ *WG-IV-2015 – item 6.2*	
2.10	PT 8: Should the city scenario be used and replace current scenarios in the OECD ESD for PT 8? ⇒ *WG-IV-2015 – item 6.2*	NL volunteered to take over this point. **Discussion at AHEE-1, endorsement scheduled for WG-IV-2016.**
2.11	PT 21: How to use data on background concentrations in the env. risk assessment ⇒ *WG-IV-2015 – item 6.3 (reference below the DTs to the respective RCOM table entries)*	FR volunteered to take over the item.
2.12	PT 18: Development of equations to take into account degradation in manure ⇒ *WG-V-2015 – item 7.2b*	NL volunteered to take over this point. **Discussion at AHEE-1, NL will provide revised document to SECR by 1 July 2016. Endorsement scheduled for WG-IV-2016.**
2.13	PT 6: Development of an emission scenario for the preservation of unrefined fuels ⇒ *WG-V-2015 – item 7.3*	AHEE member to take over item to be assigned – low priority for the time being
2.14	Clarification on DT50 values according to the FOCUS guidance to be used for modelling purpose and as trigger value (for higher tier studies/PBT assessment) ⇒ *WG-I-2016 – item 6.3b*	**DE/UK** volunteered to take over the item (update of PBT guidance to be taken into account).
2.15	Development of RTU/small scale application scenario for PT 18 (household and professional use) ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.16	Development of a proposal on how to use Fsim in an aggregated exposure assessment for PT 18 ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.17	Proposal on exposure assessment of metabolites in the terrestrial compartment ⇒ *WG-II-2016 – item 6.4*	DE will prepare a proposal for discussion. **Discussion at AHEE-1, endorsement scheduled for WG-IV-2016.**
2.18	*Refinement options for PT 11 once through and large recirculating systems*	AHEE member to take over item to be assigned – document form industry awaited.

No.	Title (current leader)	Status
	⇒ *WG-II-2016 – item 6.8/6.9*	

List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MŰHLE Ulrike (DE)
WEBER Philippe (FR)
GATOS Panagiotis (GR)
HUIZING Tjaart-Jan (NL)
HUSZAL Sylwester (PL)
WARBURTON Anthony (UK) Rapporteur
Rapporteurs
BOITIER Caroline (FR)
MEDJO-BYABOT Corettie (FR)
Flexible members
KORKOLAINEN Tapio (FI)
KARHI Kimmo (FI)
CATALDI Lucilla (IT) Rapporteur
Applicants
Thor
Lanxess
Lonza

Endura S.p.A.
Evonik
Biofa AB
Knoell
Albermale
Croda
University of Applied Science Steinfurt
ECHA Staff
KREBS Bernhard (Chair)
RODRIGUEZ UNAMUNO Virginia
AIRAKSINEN Sanna
GLANS Lotta
LISBOA MARTO Susana

Human Health WG

Core members
MAXIMILIEN Elisabeth (FR)
DE SAINT-JORES Jeremy (FR)
HOLTHENRICH Dagmar (DE)
KNEUER Carsten (DE)
BOS Carina (NL)
ARAPAKI Niki (EL) – alternate member
KOSHY Lata (UK) – alternate member and Rapporteur
Rapporteurs
CABELLA Renato (IT)
BOITIER Caroline (FR)
MEDJO-BYABOT Corettie (FR)
WOBST Birgit (DE)
Flexible members
MIKOLAS Jan (CZ)
PETERSEN Annika Boye (DK)
PALOMÄKI Jaana (FI)
KARHI Kimmo (FI)
HÄMÄLÄINEN Anna-Maija (FI)
REY Marion (FR)
UJMA Monika (PL)
ROSSIER Nadine (CH)
Advisors
DEARSLY Louise (UK)

ECHA Staff
AIRAKSINEN Antero (Chair)
ANTAL Diana
ESTEVAN MARTINEZ Carmen
JANOSSY Judit
MYÖHÄNEN Kirsi
PECORINI Chiara
RUGGERI Laura
BUEHLER Dominique
SCHAKIR Yasmin
Applicants
Thor
Euro Chlor
Lanxess
Lonza
Evonik
Biofa AB
BELGAGRI
Stakeholders
COREA Namali – CEFIC (only for non-confidential items)

Efficacy WG

Core members
ATTIG Isabelle (FR)
GIATROPOULOS Athanasios (EL)
LEPAGE Anne (BE)
GERRITSEN Lonne (NL)
ESCH Daniel (DE) remotely - Rapporteur
O'HANLON Richard (IE)
DUH Darja (SI)
HAMEL Darka (HR)
Flexible members
HORNEK-GAUSTERER Romana (AT)
VOGEL Birte (DK)
VÄLIMÄKI Elina (FI)
KAUKONIEMI Sanna (FI)
FRANK Ulrike (SE)
ROSSIER Nadine (CH)
JOHNSON Amy (UK) - Rapporteur

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
SCHAKIR Yasmin
Applicants
Thor
Lanxess
Lonza
Biofa AB
Belgagri
Pulcra Chemicals LLC
Rapporteurs
BOITIER Caroline (FR)
MEDJO-BYABOT Corettie (FR)
Stakeholders
HADINGHAM Timothy (CEFIC) – only for open session

Environment WG

Core members
LEFÈBVRE Frederic (BE)
KANDRIS Ioannis (GR)
ALEXANDRE Stéphanie (FR)
CHION Béatrice (FR)
PETERSOHN Eleonora (DE)
MUIJS Barry (NL)
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A MARCA Maria (CH)
MUNCH CHRISTENSEN Anne (DK)
JENSEN Pia Haugaard DK)
PASANEN Jaana (FI)
PENTTINEN Sari (FI)
DIAS Victor (FR)
FREIN Daniel (DE) - Rapporteur
SCHMIDT Jana (DE)
HADAM Anna (PL)
Rapporteurs
BOITIER Caroline (FR)
MEDJO-BYABOT Corettie (FR)
ANDERSON Claire (UK)
PEPPER Catherine (UK)

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SCHIMMELPFENNIG Heike (Chair)
GUTIERREZ Simon (Deputy Chair)
LAITINEN Jaana
LIPKOVA Adriana
NOGUEIRO Eugenia
SAEZ-RIBAS Monica
SCHAKIR Yasmin