Final minutes of the Working Group meeting II in 2023

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

(Meeting date: 20 to 22 June 2023 – hybrid meeting)

25 September 2023

1. Welcome and apologies

The meeting was a hybrid meeting. The Chair welcomed the participants of the working group meeting. 19 members and one stakeholder were physically present 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.

The chair reminded the participants of the purpose of the meeting.

2. Administrative issues

The chair reminded about the security rule for connecting to the meeting and informed about the physical security information distributed to all locally present participants.

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).

No modifications to the agenda were proposed.

The agenda was agreed without modifications.

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

Two comments on the minutes of WG I 2023 were received in the commenting period. The working group members reviewed and accepted the proposed changes of the draft minutes. The draft minutes were modified accordingly and were agreed by the working group members.

6. Active Substances

6.1. 2,2-dibromo-2-cyanoacetamide (DBNPA), PT 6

Please refer to the specific minutes of this agenda item.

6.2. Sulfuryl fluoride, PT 8, 18 (renewal)

Please refer to the specific minutes of this agenda item.

6.3. Early WG discussion – Alphachloralose

Please refer to the specific minutes of this agenda item.

7. Union Authorisations

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

Please refer to the specific minutes of this agenda item.

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

Please refer to the specific minutes of this agenda item.

7.3. UA for a product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) PT 11, PT 12, PT 13, PT 6

Please refer to the specific minutes of this agenda item.

7.4. UA for a product family containing L-(+)-lactic acid PT 2, PT 3, PT 4

Please refer to the specific minutes of this agenda item.

8. Technical and guidance related issues

8.1. Update of the APCP TAB

The WG discussed changes to the APCP TAB that are intended to clarify the text without changing the content documented. The agreed changes will be incorporated into a new TAB version.

8.2. New proposed TAB entries

The WG discussed concrete text proposals for inclusion into the APCP mostly based on earlier WG discussion which have not previously been considered for inclusion. The agreed changes will be incorporated into a new TAB version.

8.3. Requirements for complete composition in BP

This agenda point was added to clarify which level of detail regarding the composition is required by different member states for the assessment of a biocidal product, triggered by a different understanding between NL and ECHA, whether information provided in SDS needs to be considered sufficient.

The WG agreed that for certain waiving arguments for physical hazards, complete compositional information is required. The practices in different member states were collected.

In conclusion the APCP WG considered the requirement for complete composition sufficiently clear in the APCP subject area. What level of compositional detail required for the environmental of toxicological assessment of a biocidal product cannot be assessed by the APCP WG. This question should be referred to the ENV and TOX WG respectively.

8.4. Read-across possibilities for SADT

The working group reviewed a proposal how read-across for SADT and organic peroxide classification could be treated. There were a few proposals for refinement of the text regarding

- The requirement for SADT data for classification, which should be revised to indicate that SADT is always needed to decide on temperature control and only sometimes for classification
- A clarification that read-across may be possible across metaSPCs in a product family if the split of metaSPCs is not related to differences that affect the read across
- A clarification that a statement of an institute with recognised expertise in the field is only required for justificaitons going beyond those indicated already in the document.

The proposals lead to a new version which will be included in a new APCP TAB version.

8.5. Waiving of oxidising properties for simple oxides

The working group reviewed a proposal how certain metal oxide compounds could be confirmed as not having oxidising properties.

The working group discussed the possibility to set a safe threshold when to consider metal oxides not to be oxidising based on thermodynamic considerations and concluded that the current proposed threshold contains a sufficient safety margin.

The text was agreed by the WG with one minor modification. And is provided with these minutes

8.6. Global composition for in situ generated active substance

The working group considered the requirements for describing the composition of an in-situ generated active substance.

For details, please refer to the specific minutes of this agenda item.

9. AoB

9.1. Exchange on problems during evaluation (closed session)

Member states discussed general topics of interest observed during evaluation.

9.2. Experience with and aim of peer review (closed session)

The WG discussed the invitation to make the peer review process more effective. While some member states remarked on the lack of resources and required priority settings, others highlighted the opportunity that peer review also offers for on-the-job training and interacting with more experienced colleagues. Some members declared to intensify the participation in the peer review process.

9.3. Early clarification of AS identity and composition

The WG discussed and agreed in majority to the proposed early discussion of identity and composition of new AS. The WG agreed not to request new 5 batch analysis data after the date of agreement of the specification in the WG even in case the evaluation extends past the 10 year time limit of the 5 batch analysis. The WG also concluded that participation in this early agreement procedure is voluntary.

9.4. Harmonisation of e-consultations and early WG discussions

The WG took note of the template and the harmonised instructions how to apply e-consultaitons and early WG discussions. Clarification was requested whether the indicated deadlines include eventual discussions with the SECR (no, the deadlines are intended for requesting the e-consultation or early WG discussion) and who is responsible for communicating with the applicant in case the applicant is specifically mentioned in the distribution list (in any case it is the eCA who needs to communicate with the applicant).

One text proposal was made for the "follow-up" section, which will be forwarded and considered.

9.5. APCP TAB update procedure

The working group reviewd and discussed the principles how the APCP TAB should be updated in the future.

The WG agreed to identify the need for new entries to the TAB when ever possible at the end of a discussion. It will then be the responsibility of the owner/initiator of the related agenda point to draft a proposal to be discussed in a subsequent WG unless otherwise agreed.

After approval of the text by the WG, the APCP TAB will be updated and published by SECR.

9.6. Other information

The WG was informed about the latest progress with the development of the in-situ recommendations and took note of the important dates for APCP WG III 2023.

Annex 1 - List of attendees registered for the meeting

Country	**Member state participant**	
AT	Michael	GHOBRIAL
AT	Natalie	HOFMANN
AT	Erich	NEUWIRTH
AT	Dominik	ALTMANN
BE	Anastasia	BURMISTROVA
BE	Minh-Dung	DANG THY
BE	Steven	FAUCONNIER
BE	Yannick	HERREMANS
BE	Samuel	HUERGA-FERNÁNDEZ
BE	Kim	SWENNEN
CH	Michael	AESCHBACHER

CH	Amandine	COURDOUAN MERZ
CZ	Martin	VLASAK
DE	Ulrike	MÜHLE
DE	Tobias	DEDEN
DK	Maria	TRIANTAFILLOPOULOS
DK	Jeppe Juhl	CHRISTIANSEN
EE	Imre	VALLIKIVI
ES	David	CANO
ES	Jesús	ESCALADA AGUILERA
FI	Katariina	VUORENSOLA
FR	Thérèse	SIX
FR	François	LUTZ
FR	Philippe	WEBER
FR	Clément	LEBEE
LV	Julija	BROVKINA
LV	Ieva	IGAUNE
NL	Sabine	KRUIDHOF-AKERBOOM
NL	Peter	VAN RIJNSBERGEN
NL	Alena	BOURKE
NL	Inge	STORM
NL	Cornelia	BLAGA
NO	Marianne Stave	SEKKENES
NO	Ingrid Ur	GJERDE
PL	Sylwester	HUSZAŁ
PL	Anna	HORCZYCZAK
PL	Magdalena	JURASZEK
PL	Agnieszka	PODLASKA
SE	Patrik	STENSTRÖM
SE	Anh	JOHANSSON
SE	Edda	HAHLBECK
SE	Göran	MARSH
SE	Patrik	STENSTRÖM
SI	Špela	VELIKONJA BOLTA
SI	Klavdija	ZIRNGAST
SK	Zuzana	DRABOVA KUSIKOVA
SK	Denisa	MIKOLASKOVA

Accredited Stakeholder Organisations (ASOs)			
	Biocides for Europe (Cefic)	Jules	BOSSERT
	Biocides for Europe (Cefic)	Stuart	CALDWELL
	Biocides for Europe (Cefic)	Paul	WHEELER
	A.I.S.E	Marie	DARRIET
	A.I.S.E	Marie	REGNIER
	Biocides for Europe (Cefic)	Boris	VAN BERLO

Applicants	
	ICL Europe Cooperatief U.A.
	Arrow Regulatory
	Microbial Control (Switzerland)
	Exponent International Limited
	Arche Consulting
	TSG
	LANXESS Deutschland GmbH
	Chemservice S.A.
	Diversey

ECHA staff
Uphoff Andreas
Marcon Eva

Oxidizing properties of selected metal oxides

This document is meant for use by the competent authorities under BPR only to consider the acceptability to waive a test for oxidizing properties of a liquid biocidal product containing metal oxides.

Background

Antifouling paints usually contain several metal oxides as pigments. The metal oxides do not comply with the waiving criteria for oxidizing properties according to CLP as they contain oxygen bound to other elements than carbon or hydrogen. Many of the antifouling paints are non-aqueous liquids and thus, the waiving criteria for an aqueous solution containing max. 20% solid oxidizing substances is not met, either.

To consider and waive the hazard class oxidizing liquid of an antifouling paint, it is suggested to consider the oxidizing properties of the metal oxides (solids) and if the metal oxides (or any other component in the product) are not classified as oxidizing solids, the liquid product is not classified as an oxidizing liquid and no further testing is required.

The Ellingham diagram

The Ellingham diagram is a graph (Appendix 1) representing the thermodynamic driving force for a particular reaction to occur, across a range of temperatures. Thus, it shows the temperature dependence of the stability of compounds. This analysis is usually used to evaluate the ease of reduction of metal oxides and sulfides. In metallurgy, the Ellingham diagram is used to predict the products formed and the Gibbs energy application between a metal, its oxide, and oxygen.

An Ellingham diagram is a plot of ΔG (Gibbs free energy) versus temperature. Gibbs free energy, the measure of thermodynamic driving force of a reaction, can be written as $\Delta G = \Delta H - T \cdot \Delta S$. Since ΔH (enthalpy) and ΔS (entropy) are essentially constant with temperature unless a phase change occurs, the free energy versus temperature plot can be drawn as a series of straight lines, where ΔS is the slope and ΔH is the y-intercept. The slope of the line changes when any of the materials involved melt or vaporize.

Gibbs free energy of formation is negative for most metal oxides, and so the diagram is drawn with $\Delta G=0$ at the top of the diagram, and the values of ΔG shown are all negative numbers. Temperatures where either the metal or oxide melt or vaporize are marked on the diagram.

The Ellingham diagram is for metals reacting to form oxides. The oxygen partial pressure is taken as 1 atmosphere, and all of the reactions are normalized to consume one mole of O_2.

One of the three main uses of the Ellingham diagram is to determine the relative ease of reducing a given metallic oxide to metal (and thus the oxidation of carbon by the metal oxide). The position of the line for a given reaction on the Ellingham diagram shows the stability of the oxide as a function of temperature. Reactions closer to the top of the diagram are the most “noble” metals (for example, gold and platinum), and their oxides are unstable and easily reduced. As we move down toward the bottom of the diagram, the metals become progressively more reactive, and their oxides become harder to reduce. A given metal can reduce the oxides of all other metals whose lines lie above theirs on the diagram. Due to the negative slope of carbon line, carbon is a useful reducing agent for many metal oxides.

It should be noted that the Ellingham diagram is constructed based only on thermodynamic considerations and therefore gives information about the thermodynamic feasibility of a reaction. It does not tell anything about the rate of the reaction.

Selected metal oxides and their oxidizing properties

The information from Ellingham diagram for metal oxides often found in anti-fouling paints has been considered and the metal oxides are categorized into two groups:

(1) The first group includes the metal oxides for which it is safe to conclude that the metal oxide is not oxidizing, and no further test is needed.

(2) The second group of metal oxides includes those metal oxides that are considered as borderline cases and/or having oxidizing properties and for which waiving is not possible.

Additionally, information on the redox potentials of the metals has been included as supportive information (see Appendix 2).

1 Metal oxides safely considered as non-oxidizing

Titanium dioxide and silicon dioxide are known to be non-oxidizing in character and thus, any metal oxide whose Ellingham diagram is below those of titanium and silicon are safely considered as non-oxidizing (i.e., aluminium oxide, calcium oxide and zirconium oxide). The Feldspar-group minerals are considered as oxides of silicon.

For Molybdenum trioxide (MoO_3), experimental data (UN Test O.1, GLP study) is available in the REACH registration dossier which shows Mo_3 to be non-oxidizing. The non-oxidizing properties of zinc oxide (ZnO) are reported in the REACH registration dossier, justified by a calculation method.

The Ellingham diagrams of sodium and potassium oxides are below the line of molybdenum trioxide. Thus, based on the basic principle of the Ellingham diagram, sodium and potassium oxides are considered as non-oxidizing, too.

Substance	**CAS**	**Formula**
Considered as non-oxidising		
Titanium dioxide	13463-67-7	TiO_2
Silicon dioxide	112945-52-5	SiO_2
Calcium oxide	1305-78-8	CaO
Aluminum oxide	1344-28-1	Al_2O_3
Sodium oxide	1313-59-3	Na_2O
Potassium oxide	12136-45-6	K_2O
Zirconium oxide	1314-23-4	ZrO_2
Feldspar-group minerals	68476-25-5	$KAlSi_3O_8$ $NaAlSi_3O_8$ $CaAl_2Si_2O$
Zinc oxide	1314-13-2	ZnO
Molybdenum (VI) oxide	1313-27-5	MoO_3
Tungsten trioxide	1314-35-8	WO_3

2 Metal oxides considered as borderline cases and/or oxidizing

Metal oxides whose Ellingham diagram is above of that of molybdenum trioxide should be considered for classification as oxidizing as there is insufficient evidence of their non-oxidizing properties.

Substance	CAS	Formula
Borderline cases, should be considered for classification		
Cuprous oxide/ dicopper oxide	1317-39-1	$Cu(I)_2O$
Iron (III) Oxide	1309-37-1	$Fe(III)_2O_3$
Iron hydroxide oxide	51274-00-1	Fe(III)O(OH)

3 Exceptional cases: sulphates

In literature, there is limited information on the oxidizing properties of simple sulphates such as Na_2SO_4, K_2SO_4, $CaSO_4$. The Ellingham diagram available for sulfates considers the oxidation of lower metal oxides by SO_3, which is an oxidizing agent. Thus, to make a judgement on the oxidizing properties of simple sulphates, Ellingham diagram is not directly applicable.

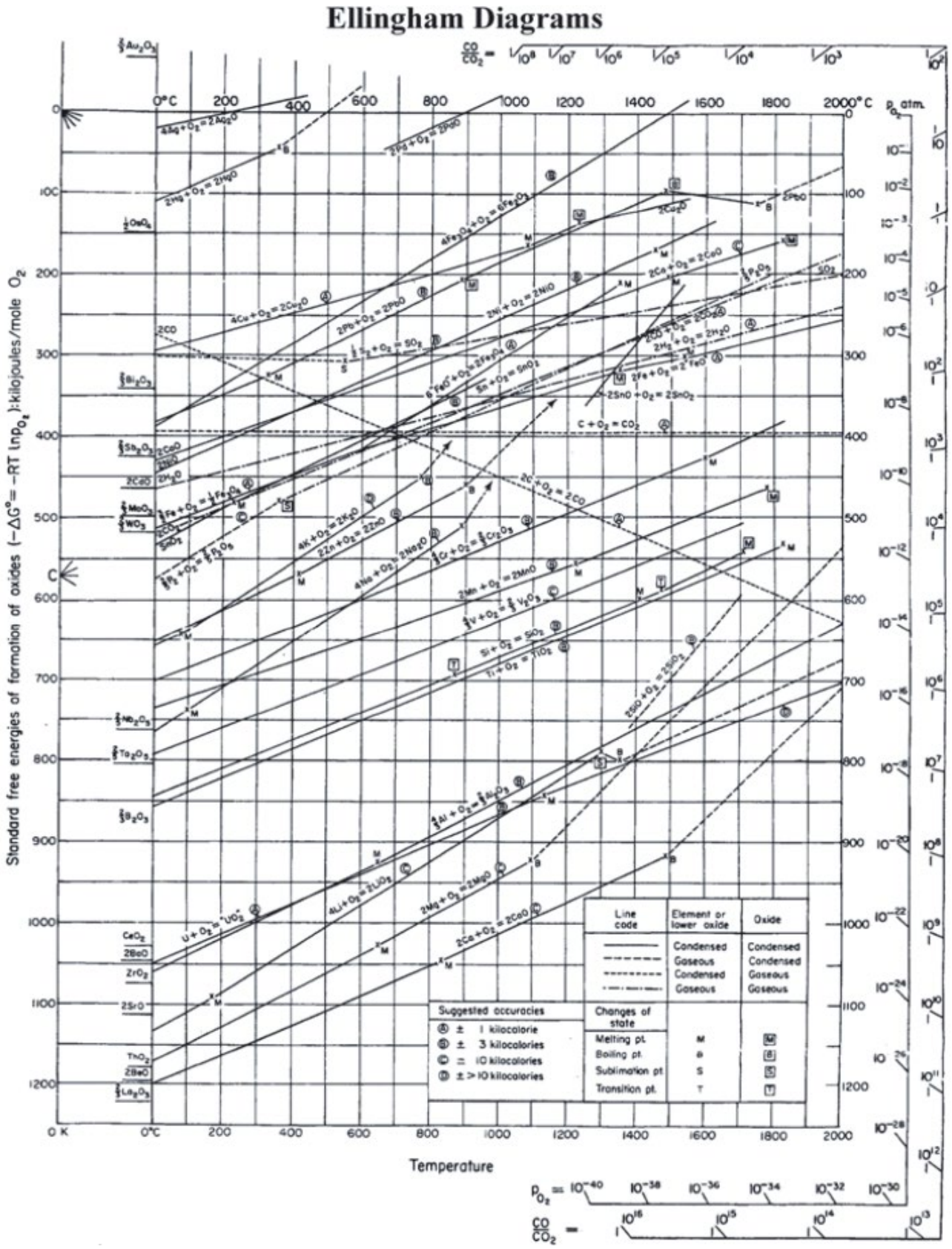
Based on common practice and experience in evaluation, it has been generally accepted by the MS experts that the simple sulphates are non-oxidizing. Thus, no further testing for oxidizing properties of a biocidal product is needed based on simple sulphates in the product.

Further information

- University of Cambridge:
  https://www.doitpoms.ac.uk/tlplib/ellingham_diagrams/printall.php

  The web site also contains an interactive Ellingham diagram tool to see the diagrams for selected metal oxides.

Appendix 1: Ellingham diagram



Appendix 2: Redox potentials of selected substances

As a supporting information to justify the non-oxidizing properties of some of the metal oxides, the redox potentials of selected substances are included. As a reference, the redox potentials of the reference substances used in UN Test O.1 (oxidizing solids) and UN Test O.2 (oxidizing liquids) are presented.

Redox potential for nitric acid (HNO_3) (reference substance in oxidizing liquid test, category 3)

- $NO_3^-(aq) + 4H^+ + 3e^- \rightleftharpoons NO(g) + 2H_2O(l)$ (0.958 V)

Redox potential for bromate (BrO_3^-) (reference substance in oxidizing solid test, categories 1-3)

- $BrO_3^- + 5H^+ + 4e^- \rightleftharpoons HBrO(aq) + 2H_2O$ (1.45 V)
- $2BrO_3^- + 12H^+ + 10e^- \rightleftharpoons Br_2(l) + 6H_2O$ (1.48 V)

Redox potentials for metals safely considered as non-oxidizing

Substance	CAS	Structure	Half reaction	Redox potential (V)
Titanium dioxide	13463-67-7	TiO_2	$Ti^{2+} + 2e^- \rightleftharpoons Ti(s)$	-1.63
Silicon dioxide	112945-52-5	SiO_2	$SiO_2(s) + 4H^+ + 4e^- \rightleftharpoons Si(s) + 2H_2O$	-0.91
Calcium oxide	1305-78-8	CaO	$Ca^{2+} + 2e^- \rightleftharpoons Ca(s)$	-3.8
Aluminium oxide	1344-28-1	Al_2O_3	$Al^{3+} + 3e^- \rightleftharpoons Al(s)$	-1.662
Sodium oxide	1313-59-3	Na_2O	$Na^+ + e^- \rightleftharpoons Na(s)$	-2.71
Potassium oxide	12136-45-6	K_2O	$K^+ + e^- \rightleftharpoons K(s)$	-2.931
Zirconium oxide	1314-23-4	ZrO_2	$ZrO_2(s) + 4H^+ + 4e^- \rightleftharpoons Zr(s) + 2H_2O$ $Zr^{4+} + 4e^- \rightleftharpoons Zr(s)$	-1.553 -1.45
Feldspar-group minerals	68476-25-5	$KAlSi_3O_8$ $NaAlSi_3O_8$ $CaAl_2Si_2O$	$Al^{3+} + 3e^- \rightleftharpoons Al(s)$ $K^+ + e^- \rightleftharpoons K(s)$ $Ca^{2+} + 2e^- \rightleftharpoons Ca(s)$	-1.662 -2.931 -2.868
Zinc oxide	1314-13-2	ZnO	$Zn^{2+} + 2e^- \rightleftharpoons Zn(s)$	-0.7618
Molybdenum (VI) oxide	1313-27-5	MoO_3	$MoO_3 + 6H^+ + 6e^- \rightleftharpoons Mo(s) + 3H_2O$ $Mo^{3+} + 3e^- \rightleftharpoons Mo(s)$	0.075 -0.200
Tungsten trioxide	1314-35-8	WO_3	$WO_3 + 6H^+ + 6e^- \rightleftharpoons W(s) + 3H_2O$	-0.090

Redox potentials for metals considered as borderline cases and/or oxidizing

Substance	CAS	Structure	Half reaction	Redox potential (V)
Cuprous oxide/ dicopper oxide	1317-39-1	$Cu(I)_2O$	$Cu_2O(s) + H_2O + 2e^- \rightleftharpoons 2Cu(s) + 2OH^-$ $Cu^+ + e^- \rightleftharpoons Cu(s)$	-0.36 0.52
Iron (III) Oxide	1309-37-1	$Fe(III)_2O_3$	$Fe_2O_3(s) + 3H_2O + 2e^- \rightleftharpoons 2Fe(OH)_2(s) + 2OH^-$ $3Fe_2O_3(s) + 2H^+ + 2e^- \rightleftharpoons 2Fe_3O_4(s) + H_2O$	-0.86 0.22
Iron hydroxide oxide	51274-00-1	Fe(III)O(OH)	$Fe3^+ + 3e^- \rightleftharpoons Fe(s)$	-0.04

Working Group – Analytical methods and Physico-Chemical Properties (APCP) to the Biocidal Products Committee

global composition for in situ generated active substance

Final minutes –WG II 2023_ 8.6

Meeting date	20 June to 22 June 2023
Active substance	0Bglobal composition for in situ generated active substance
eCA	AT, FI
Document drafted by	ECHA
Agenda point	8.6

Background

Points 1 and 2:

Please find a summary of the results of the Austrian e-consultation on the setting of a global composition in the document "WG II 2023_APCP_8-6_global composition for in situ generated active substance_proposal_AT.docx". For most of the questions the five commenting members (BE, FI, FR, NL, SK) agreed on one option. In short, the global composition should be based on concentration ranges, only constituents of the active substance need to be considered (not co-formulants) and minor reaction products may not need to be analysed if a scientifically sound worst-case estimate can be delivered. Questions 2 and 5 received mixed comments which did not allow to draw a conclusion, therefore they were discussed during APCP WG I 2023. Based on the conclusions, the two questions were adapted and are listed below.

Points 3 and 4:

Please find a summary of the results of the Finnish e-consultation on the analytical requirements for active chlorine generated by electrolysis in the background paper "WG II 2023_APCP_8-6_ global composition for in situ generated active substance_FI.docx". The results of the e-consultation did not allow to draw conclusions on the questions, so they were discussed in APCP WG I 2023. Based on that discussion, a resolution for both remaining questions is proposed below.

Draft minutes – 0Bglobal composition for in situ generated active substance			
a) No	**b) Issue and background**	**c) WG discussion**	**d) Conclusions and action points**
1.	**AT** Do you agree that impurities stemming from precursor substances do not need to be included in the global composition (if already addressed within precursor specifications)? Proposal: Significant and relevant impurities of the in situ generated active substance (isAS) need to be specified in the Global composition (GC). It is proposed as for conventional active substances not to state impurities present at <0.1 % w/w based on dry weight regardless of whether they are stemming from precursors in the isAS or not. **To be discussed:** Does the WG agree to the proposal?	The WG discussed whether it is better to mention non-reacting impurities stemming from precursors only in the reported composition of the respective precursor or whether they should be repeated also in the global composition of the isAS. The WG agreed that it is clearer to consider the global composition independent of the precursors and potentially repeat non-reacting impurities. The WG agreed on the proposal by AT. The requested extract from the draft in-situ recommendations can be found in an annex to these minutes.	**Point closed** **Conclusion:** Agreed. **Action points (deadlines):** ECHA to check the in-situ document for how it is defined.
2.	**AT** Do you agree that the global composition for an in-situ active substance shall be based on the highest concentration possible with the used generation system, including the solvent? In case of application in a washing machine this would correspond to the concentration in the premixing vessel (before dosing) if present. Proposal: The highest concentration available with the used generation system will be taken as the active	The WG discussed and clarified that the global composition is intended to describe the range of compositions possible for the isAS. The WG agreed with the proposal with the understanding that the highest available concentration should be understood as the upper limit of this range.	**Point closed.** **Conclusion:** Agreed. **Action points (deadlines):**

Draft minutes – 0Bglobal composition for in situ generated active substance			
a) No	**b) Issue and background**	**c) WG discussion**	**d) Conclusions and action points**
	substance to be reported in the global composition (including the solvent). As the possible high dilution would lead to a lack of information on the composition, the identification of significant impurities will be considered on the basis of dry weight for isAS. **To be discussed:** Does the WG agree to the proposal?		
3.	**FI** **Requirements for complete analysis of active chlorine generated from sodium chloride by electrolysis** **Expected impurities** **Proposal:** In addition to active chlorine, chlorate, bromate and unreacted sodium chloride (option a), all expected species in the active substance *active chlorine generated from sodium chloride by electrolysis* must be analyzed if they are significant or relevant. The significant impurity refers to dry weight. **To be discussed:** Does the WG agree to the proposal?	The WG agreed to the proposal realising it is very similar to item 1 in this discussion table.	**Point closed.** **Conclusion:** Agreed (similar conclusion as for point 1) **Action points (deadlines):**

Draft minutes – 0Bglobal composition for in situ generated active substance			
a) No	**b) Issue and background**	**c) WG discussion**	**d) Conclusions and action points**
4.	**FI** **Requirements for complete analysis of active chlorine generated from sodium chloride by electrolysis** **Impurities originating from water** **Proposal:** All constituents of the water used in the electrolysis process *per se* need not be analyzed but all constituents that are transformed during the electrolysis process must be considered and analyzed if significant or relevant. The significant impurity refers to dry weight. **To be discussed:** Does the WG agree to the proposal?	The WG discussed that the quality of water used should be described and a justification provided which constituent can or cannot react under the conditions of the in-situ generation system. The WG agreed to the proposal with the above addition.	**Point closed.** **Conclusion:** Agreed. Include a remark that the quality of the water needs to be included in the CAR and PAR. **Action points (deadlines):**

Annex I extract from the draft in-situ recommendations

Active substance generated *in situ (*or *in situ* generated active substance) comprises the pure active substance, impurities and solvent(s) that cannot be separated without affecting the stability of the *in situ* generated active substance. It is the output of the in situ generation system.
Global composition of the active substance generated *in situ* describes the qualitative and quantitative composition which should be covered by the approval dossier. The global composition should be proposed by the applicant(s) that have submitted the application for active substance approval. The following elements must be taken into account by the applicant and verified by the eCA.

- Variations of the qualitative and quantitative compositions[1] due to variations in the amount of applied precursor(s) or performances of the applied device(s).
- Analytical information must be sufficient to confirm the proposed global composition.
- The applicant has to justify that the test materials applied for toxicological and ecotoxicological tests are covered by the proposed global composition.
- The global composition should be adjusted where appropriate due to the toxicological and ecotoxicological evaluations.

In situ generated **pure** active substance (pAS) (or pure active substance generated *in situ*) refers to one or several chemical compound(s) (generated *in situ*) which exert biocidal activity. The **pure** active substance generated *in situ* **does not** include impurities, additives or any solvent. If additives and/or unreacted precursor(s) are active substances on their own, these additives and/or unreacted precursors will not be regarded as part of the pure active substance generated *in situ*; in such cases additives and unreacted precursors are not impurities but pure active substances on their own.
Impurities (I) are the non-active part of the active substance generated *in situ*. Impurities are not intentionally added to the precursor or the *in situ* generated active substance. Impurities can be divided into the following groups:

- Unreacted precursor(s)
- Impurities and solvents which are present in or part of the precursor(s) or precursor(s) mixture and transferred to the active substance generated *in situ.*
- Constituent(s) as a result of unintended and/or unwanted and/or secondary and/or incomplete reactions during *in situ* generation.
- Reaction by-products which are formed by complete or incomplete reaction(s) of the precursor(s) or precursor(s) mixture and its impurities during the *in situ* generation. This includes reactions of the precursor(s) and its impurities with the solvent or matrix during the in situ generation, e.g. reactions with components present in seawater when used as a precursor, reactions with co-formulants present in the biocidal product.

Disinfection by-products (DBP) are **not impurities** and cannot be considered as reaction by-products as defined above. Components formed during the intended use of the in situ generated active substance are not regarded as reaction-by-products. **Disinfection by-products are not addressed in this document**.

[1] Qualitative and quantitative composition relates to all chemical identities of the constituents and their concentration (ranges) present in the in situ generated active substance.

WG-II-2023

Final minutes

19 September 2023

Final minutes of Efficacy WG-II-2023

20-22 June 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) hybrid meeting and informed them that this meeting is split into three consecutive 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 had sent comments on the EFF WG-I-2023 draft minutes. The revised draft minutes of WG-I-2023 were agreed at the meeting.

6. Discussion of active substances

6.1 2,2-di2,2-dibromo-2-cyanoacetamide (DBNPA) (eCA DK)

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

6.2 Sulfuryl fluoride (eCA SE)

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

6.3 Early WG discussion on free radicals generated in situ from ambient air or water (eCA NL)

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

6.4 Early WG discussion on chlorine dioxide generated from tetrachlorodecaoxide complex (TCDO) by acidification (eCA DE)

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 Hydrogen peroxide (eCA NL)

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 (eCA NL)

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

7.3 UA for a product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) (eCA NL)

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

7.4 UA for a product family containing L-(+)-lactic acid (eCA LV)

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

7.5 Early WG discussion on UA-APP containing C(M)IT/MIT (eCA NL)

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

8. Technical and guidance related issues

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

The revised proposal was introduced by DE. Some amendments were suggested by the WG members during the discussion, e.g. how to define the application rate (tier 2 data takes precedence), the possibility to waive tier 2 studies for curative uses and target organisms (all) need to be tested also in tier 2 tests. It was also clarified that tier 2 tests are not relevant for PT 11 and 12 uses the WG is aware of, as the matrix for these uses is usually fresh. Possible cases where pre-treatment of the matrix is relevant for the use can be decided on a case-by-case basis.

The updated TAB proposal will be revised, sent for commenting and presented at the next WG meeting.

8.2 TAB proposal - Defining growth in untreated controls (DE)

TAB proposal was introduced by DE. The draft was prepared according to the definition of growth included in the PT 11 and 12 guidance and agreed upon by the WG. It is applicable to PTs and all uses where growth is required in the untreated control and is measured by CFU quantification. There was a minor concern that the requirement of statistical significance might be difficult to achieve, nevertheless, the proposal is in line with the IBRG methods. It was clarified that the comparison of the number of organisms between recovery after the inoculation (t=0) and measurement after the incubation period (e.g. t=7 d) will be made after each challenge when multiple inoculations are made. In cases where more than one challenge is performed, growth (increase) needs to be shown at least after one of the challenges. The generation time or the growth rate of the target organisms are not affecting the results as the incubation periods are normally long in the challenge tests.

The agreed TAB entry is presented below:

What are the minimum requirements for growth in untreated controls when quantified as CFU?

Growth means an increase over the recovery directly after inoculation, which is statistically significant and greater than 0.5 log. Statistical significance is usually determined by Student's t-test. A p-value <0.05 (95 % confidence level) is highly recommended, p <0.1 (90% confidence level) may in exceptional cases be used if justified (e.g. identifying outliers, or lowest concentration with a biocide showing growth).

8.3 TAB proposal - PT1-5 Use concentration and contact time (NL)

There were no major objections to the presented draft. However, it was pointed out by one MS that the proposal needs to state clearer that it refers to one specific use as the product may have several uses and as such the TAB entry may be misinterpreted. In addition, the title should be amended to be more general.

ECHA will revise the draft in accordance with the received feedback and present it at the next EFF WG meeting.

9.4 Conditions for authorisation of PT19 products against ticks (and other invertebrates) when the mortality within the respective CPT exceeds 10%

The discussion was initiated by SI and referred to proof of a non-insecticidal effect of the repellent product. According to the efficacy guidance for repellents against invertebrates, the mortality in the treatment group should be similar to the control group and if mortality in the treatment group exceeds 10%, justification from the applicant is needed. In general, the insecticidal effect on non-target organisms should not happen as the intention is to protect them. The discussion focused on the justification which may be accepted in such a case with reference to the target organisms. It was pointed out that proof should be

provided for an adverse/unpleasant effect of the repellent, e.g. repellent applied in restaurants against cockroaches shouldn't have an unpleasant effect on the customers (visible dead bodies of cockroaches). Due to limited expertise, for the time being, the acceptance should be done on a case-by-case basis. For the case in question, the mortality of the target organisms should be accepted. It was noted that in some cases the mortality might have a positive effect on the customers, e.g. in the case of mosquito repellent. During the decision-making process it is necessary to take into account the intended use of the product (mortality cannot be innate to the product) and the target organisms claimed. For the case in question, the mortality of the target organisms should be accepted.

With reference to the acceptable mortality level, the acceptance should also be taken on a case-by-case basis. This is not an optimal approach as it may lead to unintentional inconsistencies. For the case in question, a mortality of 20% seems to be acceptable.

9. AOB

9.1 Harmonisation of e-consultations and early WG discussions

ECHA presented a document addressing the practices and terminology of e-consultations and early Working Group (WG) discussions. There were no major objections, one MS suggested amending the following sentence 'It has to be noted that the purpose of an early WG discussion is not to verify the evaluation made by the eCA already before the submission of the dossier for the opinion-forming process' a bit clearer by clarifying that it refers to the final evaluation. This comment will be forwarded to the other authors of this document and discussed internally.

9.2 Other information.

A brief update on the upcoming EFF WG-III-2023 meeting was provided including the deadlines for the early WG discussion requests and working documents submission. In addition, ECHA shared several updates related to:

- next activities concerning guidance update,
- e-consultations,
- overdosing issue, and
- updates from CEN.

Annex 1

Efficacy WG attendees

Country	Member state participant	
AT	Bernhard	WIDHALM
AT	Natascha	BURGER
BE	Abla	ANENE
BE	ANNE	LEPAGE
BE	Jennifer	PIROTTE
BE	Minh-Dung	DANG THY
BE	Natania	PEELMAN
CH	Eliane	WANDELER
CH	Gérard	DONZÉ
CH	Manuel	RUSCONI
CH	Margrith	MEIER
CH	Rebekka	BAUMGARTNER
CZ	Katerina	DOLEŽELOVÁ
CZ	Roman	SVEJSTIL
DE	Irina	JANSEN
DE	Juliane	FISCHER
DE	Martin	KRÜGER
DE	Ute	TRAUER-KIZILELMA
DK	Charlotte Cleyton	JØRGENSEN
EE	Grethe-Johanna	PLOOMPUU
EL	ARGYRO	AMPATZI
EL	Athanasios	GIATROPOULOS
ES	Cristina	PORTELA
FI	Sanna	KAUKONIEMI
FI	Timo	NIEMINEN
FR	Isabelle	ATTIG
FR	Mathias	BRIZARD
FR	Nabila	HADDACHE
FR	Yann	MAXIMILIEN
IE	Aoife	OWENS
IE	Helen	LYNCH
IT	Lucilla	BALDASSARRI
IT	Maria Beatrice	RONCI
LV	Julija	BROVKINA

LV	Linda	MEZULE
NL	Bas	DEKKERS
NL	Hanneke	WIGGERS
NL	Sonja	WARMERDAM
PL	Iga	DALIDOWSKA
SE	Bengt	ÅSLING
SI	Darja	DUH
SK	Emese	DANADAIOVÁ
SK	Juliana	JASSOVA

ECHA Staff	
Katarzyna	SZYMANKIEWICZ (Chair)
Mari	RAULIO
Anni	HONKA
Eva	HAMALAINEN
Liridona	HAMITI

Accredited Stakeholder Organisations (ASOs)		
Biocides for Europe (Cefic)	Jules	BOSSERT
A.I.S.E	Hannah	CORNER
A.I.S.E	Elaine	BLACK
A.I.S.E	Mara	MORENO
A.I.S.E	Marie	DARRIET
Biocides for Europe (Cefic)	Lucie	PALMA
Biocides for Europe (Cefic)	Romuald	RICHARD
Biocides for Europe (Cefic)	Boris	VAN BERLO
Biocides for Europe (Cefic)	Sophia	HASENJÄGER
Biocides for Europe (Cefic)	Ellen	THOM
Biocides for Europe (Cefic)	Lorraine	WOOLLEN

Applicants
TCDO Produktionsgesellschaft mbH
SCC GmbH
LANXESS Deutschland GmbH
Troy
Arche Consulting
TSG
Chemservice S.A.
Diversey

Human Health WG-II-2023

Final minutes

19 September 2023

Final minutes of Human Health WG-II-2023

20-22, 27 June 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 71 members or advisers registered, of which 14 were (alternate) core members. Three stakeholder representatives and three experts were registered. Applicants were registered for their specific substance 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, and all meeting participants need to be registered.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The agenda was agreed without changes.

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

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

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

The minutes were agreed without further changes.

6. Active substances

6.1 2,2-di2,2-dibromo-2-cyanoacetamide (DBNPA), PT 6 (eCA DK)

The assessment performed in early product types was not questioned and only minor changes were agreed in the CAR.

6.2 Sulfuryl fluoride, PT 8, 18 (eCA SE)

The information was insufficient to conclude on developmental neurotoxicity and endocrine disruptive properties. An additional assessment factor of 10 was agreed for the AEC values.

6.3 Early WG discussion – Performic acid generated from formic acid and hydrogen peroxide, PT 2, 4, 11, 12 (eCA BE)

The proposed waiving was agreed for skin corrosion and irritation, eye irritation, skin sensitisation and acute toxicity. Further testing is needed on in vitro mutagenicity, with possible follow-up. Before deciding on higher tier testing, an ex vivo study was supported as proposed by the eCA.

6.4 Early WG discussion – TCMTB ((benzothiazol-2-ylthio) methyl thiocyanate), PT 9, 12 (eCA NO)

The stepwise approach proposed by the eCA for the assessment was supported.

7. Union authorisation applications

7.1 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.

7.2 UA for a product family containing Hydrogen peroxide, PT 2 (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 family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT), PT 6, 11, 12, 13 (eCA NL)

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

7.4 UA for a product family containing L-(+)-lactic acid, PT 2, 3, 4 (eCA LV)

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 Local risk assessment - Vol III Parts B+C guidance revision

Following an e-consultation, SECR brought several topics for a preliminary discussion at the WG to receive feedback on how the guidance should be revised. No final conclusions were made, and SECR will take all input into account in preparing a draft for consultation.

8.2 EN standards

An open discussion took place regarding the requirement to assign an EN standard (or equivalent) when prescribing personal protective equipment.

The members generally do not have access to EN standards and they do not have expertise for assigning an appropriate standard. It was noted that the assignment of a protection factor is important, while the EN standard was seen as less relevant for safe use, also noting that an EN standard would not define e.g. the protection factor or material of the PPE/filter, and it is not straightforward to translate the necessary protection to an EN standard. It was also asked whether conclusions on RMM can be made by the WG, as normally this is done by the BPC.

It was noted that further work is needed to provide the appropriate principles and guidance if the WG should conclude on appropriate EN standards for PPE. ECHA and Commission will discuss the issue bilaterally.

9. Any other business

9.1 Harmonisation of e-consultations and early WG discussions

SECR had provided a document to harmonise the concepts and practices regarding e-consultations and early WG discussions in all WGs. The members generally supported the document and only some clarifications were requested. SECR will discuss the suggestions to ensure acceptability for all WGs. It is expected that document will be published during summer 2023.

9.2 Other information

WG minutes search

SECR had provided a search tool for the WG minutes and launched an e-consultation to get feedback on the tool. The tool is available only to MSCAs because it contains all WG minutes, including confidential information.

In response to some problems reported in the e-consultation, SECR had prepared revised instructions. At the meeting, SECR asked feedback from the members in using the tool.

Some members informed that the tool is functioning as planned, while others had not had the time to test with the new instructions. SECR asked the members to send feedback by e-mail and inform whether the problems are solved, noting that it is necessary to verify that the tool is functioning as intended before providing the tool to all the WGs.

Ongoing *in-situ* recommendations development

SECR reported of the current state of play in the *in-situ* guidance development, in particular as regards the work on the human health sections for in-situ generated active substances and for the products generating these. SECR also outlined the next steps envisaged by Q2/2024, including the expected CA meeting discussion on identified outstanding issues in September, followed by a potential further update of the compiled draft guidance, joint WGs-ASOs consultation on the updated guidance version in November-December and endorsement expected in APCP/EFF/HH/ENV WG-I-2024. Finalisation and publication of the guidance is envisaged in Q2/2024.

Revision of ECHA Guidance Vol III Parts B+C

Members took note of the provisional timeline for this guidance revision with expected publication of the updated guidance in December 2024, pending the progress also in the revision of the CLP Regulation, CLP guidance and REACH guidance.

EOGRTS review project

SECR informed the members of the publication of the final report[1] and Annex[2] of the EOGRTS review project, published in March 2023 and comprising the evaluation results from 55 EOGRTS under REACH.

E-consultations

The members were invited to report to the WG on the outcome of e-consultations on their cases' evaluation.

AT member briefly informed the members about the e-consultation outcome from 1) an ED assessment of one active substance case, the feedback received and the envisaged next steps in this regard, and 2) an e-consultation to confirm a reference specification of another active substance.

Active substances & revision of CLP Regulation

Members were informed that as the revised Annex I to CLP Regulation entered into force 20 April 2023 (Delegated Act), the hazard profiles of ED and PBT/vPvB substances, so far assessed by the BPC, can now be also concluded by RAC. While the analysis on its impact on BPR processes is ongoing, the updated CLH report template with new hazard

[1] https://echa.europa.eu/documents/10162/17228/final_report_eogrts_review_project_en.pdf

[2] https://echa.europa.eu/documents/10162/17228/annex_eogrts_review_report_en.pdf

classes is already available[3] and the combined CLH – CAR template update is in progress.

Functional mailboxes

SECR informed the members about the functional mailboxes that they could use, as follows:

- BPC-TOXWG@echa.europa.eu to be used for e-consultation requests, early WG requests etc.
- BPC-WGs@echa.europa.eu to be used for correspondence concerning WG organisation, membership, Interact etc., as well as when several WGs are concerned.

Seconded National Expert (SNE)

SECR encouraged the members to consider the available opportunities and express interest in joining the ECHA biocides units as seconded national experts.

Next WG meetings

The next WG meeting in 2023 will be virtual. The provisional timing is as follows:

- 18-29 September (virtual)

  For this meeting, items should be requested to be included on the agenda by 7 August (including early WG discussions).

  An e-consultation should be launched by 17 July if intended to be discussed in this meeting.

- 4-15 December (virtual)

  For this meeting, items should be requested to be included on the agenda by 23 October (including early WG discussions).

  An e-consultation should be launched by 2 October if intended to be discussed in this meeting.

[3] https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities

Annex 1

Human Health WG attendees

Country	Member state participant	
AT	Christine	HÖLZL
AT	Angelika	DERLER
AT	Ingrid	HAUZENBERGER
AT	Alexandra	FISCHER
AT	Lorenz	KARL
BE	Charlotte	TORDOIR
BE	Anis	HOUAMED
BE	Margot	VAN CAUWENBERGHE
BE	Glenn	BUVENS
BE	Lies	PEETERS
CH	David	GRÜNIG
CH	Daniela	GOLDINGER
CH	Frédéric	SANS-PICHÉ
CZ	Jan	MIKOLAS
CZ	Petr	SEDLAK
DE	Sabine	JULING
DE	Marize	MARZO SOLANO
DE	Florian	PADBERG
DE	Isabel	GÜNTHER
DE	Kristin	HERRMANN
DE	Dagmar	HOLTHENRICH
DE	Heiko	SCHNEIDER
DE	Annetta	SEMISCH
DK	Stine	JENSEN
DK	Max	HANSEN
EE	Sandra	KÄOSAAR
EL	Anastasia	REPOUSKOU
ES	José María	SÁNCHEZ
ES	Eduardo	DE LA USADA MOLINERO
FI	Elina	VÄLIMÄKI
FI	Janne	ATOSUO
FI	Anna-Maija	HÄMÄLÄINEN
FR	Mathieu	KERGUELEN
FR	Aurélie	AUBIN
FR	Valerie	BELLINGARD

FR	Elisabeth	MAXIMILIEN
FR	julia	LORI
FR	Tiffany	AMSALLEM
FR	Elodie	COLLIN
FR	Marion	REY
FR	Julia	VARET
IE	Alan	BREEN
IT	Edlira	DEKOVI
LV	Julija	BROVKINA
NL	Marcia	BODERO
NL	Suzanne	VAN DEN BERG
NL	Angelique	WELTEN
NO	Sabrina	AUVRAY
NO	Sara	KJÆRVIK
NO	Hilde	ANDERSEN
NO	Tonje	RONGVED
NO	Astrid	GAUSTAD
NO	Hilde Karin	MIDTHAUG
PL	Roman	GÓRECKI
SE	Edda	HAHLBECK
SE	Karolin	ASK BJÖRNBERG
SE	Krister	BLODÖRN
SE	Emma	PETTERSSON
SE	Ing-Marie	LERJEVIK
SI	Nataša	PETROVIČ
SI	Vladka	LEŠER
SI	Petra	ČEBAŠEK
SI	Katja	VERDNIK
SK	Dávid	DRÁB
SK	Vladimira	POLOHOVA
SK	Ružena	PILIŠIOVÁ
SK	Oľha	ROMAN

European Commission	
Lena	GRUHN
Vincent	DELVAUX

Accredited Stakeholder Organisations (ASOs)		
PSCI	Tess	RENAHAN
Biocides for Europe (Cefic)	Jules	BOSSERT
A.I.S.E	Joanna	KUPNY
Biocides for Europe (Cefic)	Florian	LÄPPLE
A.I.S.E	Marie	DARRIET
Biocides for Europe (Cefic)	Boris	VAN BERLO

Applicants
ICL Europe Cooperatief U.A.
Arrow Regulatory
Microbial Control (Switzerland)
Exponent International Limited
Kemira
Arche Consulting
Buckman Laboratories
TSG
LANXESS Deutschland GmbH
Chemservice S.A.
Diversey