Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

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Precursors and In-situ Production of Biocides under Biocidal Products Regulation (EU) No 528/2012

Industry would like to share with the Commission, ECHA and Member States mapping of existing "in situ" practices and raise its concerns with regards to the current variety of accepted practices. We would like to stress that it is not clear how today's practices will be applied under the upcoming BPR.

Summary of our concerns can be found in the following mapping table.

Existing Practice			Question/Proposed way forward	Example
1	**Chemical Reaction of Supported Precursor to Active Substance listed in the Review programme**	Both precursor(s) (all) and active substance(s) have been notified and covered in an existing Annex I Dossier	It is in line with upcoming BPR text. Historically thet interpretation was that this is in the scope of the Biocidal Products Directive (BPD 98/8/EC). Dossier under evaluation or evaluation finalised.	• Mono precursor system: Trimagnesium diphosphide releasing phosphine • **Multi precursor system: Industry is not aware of any example**
2	**Chemical Reaction of Precursor to Active Substance listed in the Review programme where:**	a) Precursor for which risk evaluation is covered in Annex I Dossier	It is in line with upcoming BPR text. *However, there is no legal recognition of precursor in BPR text. Precursors are not listed as existing active substances and have no status regarding active substances*	• TAED (tetraacetylethylenediamine) and percarbonate generating peracetic acid

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		b) Precursor for which risk evaluation is not covered in Annex I Dossier	**Who can apply for authorisation of the precursor?** ***Biocidal Product Formulator will cover missing Risk Assessment in the Biocidal Product Dossier***. In accordance with Annex VI (*Principles for the evaluation of dossier for biocidal product)* of the Biocidal Product Regulation (EU) No 528/2012 states that *"**risk assessment includes also the possible risks from the precursor(s)"*** **What is the timeline/transition for this application?** In accordance with Art 89 the Biocidal Product formulator will have 2 years (after publication date of the active substance) to submit a biocidal product dossier covering risk evaluation of the not-mentioned precursor	• Caprolactam and percarbonate generating peracetic acid
3	**Production of the Biocidal Active Substance listed in the Review programme from Basic Chemicals Using Devices**		**Who shall or may do the application for authorisation?** Could this be the : • ***Supplier/producer of basic chemical ?*** • ***Supplier/producer of device ?*** • ***Or end user?***	• Production of sodium hypochlorite and hypochlorous acid as so called electro-chemically activated water from sodium chloride (i.e. **table salt**) by **electrolysis**.
4	**Production of the Biocidal Active Substance not listed in the Review programme from Ambient sources Using Devices**		**Who shall assure active substance approval?** **Who shall or may do the application for authorisation?** • ***End user ?*** • ***Supplier/Producer of device ?***	• Production of ozone from oxygen in the air
5	**Production of the Biocidal Active Substance listed in the Review programme from Ambient sources Using Devices**		**Who shall or may do the application for authorisation?** • ***End user ?*** • ***Supplier/Producer of device ?***	• Production of Sodium Hypochlorite from sea water

Note: *This table is based on information available to A.I.S.E. and EBPF members, at the day of drafting this document. We recognize that some practices may exist in Europe but are unknown. Missing practices may need to be added to the content of the table.*

The new Biocidal Products Regulation (BPR) explicitly regulates placing on the market of biocidal products generating active substances "in situ". This might be from other chemical substances, generally referred to as precursors[1].

In order to ensure that after 1st September 2013 a harmonized approach is taken when regulating in situ generation, Industry has raised number of questions at the PA&MRFG meeting in February 2013. However, discussions did not lead to a concrete proposal on how to handle this very complex matter in the future.

Therefore we would like to reiterate our concerns and encourage the Commission to work on this urgent matter.

At this stage there is no clarity on:

- **How will the product formulators/suppliers know which precursors are included in the review programme (Active substances dossiers are confidential)?**
- **Will the list of approved active substances list precursors?**

We believe that in order to propose a harmonised way forward an extensive exercise of identifying supported systems should be conducted (in situ mapping). This will help applicants to position themselves and understand which next steps need to be taken in order to comply with new regulatory requirements.

[1] either **mono precursor systems** (only one precursor generating the active substance) or **multi precursor systems** (more than one precursor generates the active substance)