Proposal on a generic approach for the authorisation of biocidal active substances generated in situ by devices

(Proposal for designing a Biocidal Product Authorisation procedure in connection with in situ generated Active Substances for applications in PTs 1-5 (11,12) according to Regulation (EU) No 528/2012 (“BPR”))

Proposal of an integrated, generic approach

The herein presented integrated and generic approach towards the management of device-based *in situ* systems (**ISS**) with view to upcoming product authorisation is outlined in further detail in the accompanying document "***CA-Sept17-Doc.4.8.***".

Device-based in situ systems - Advantages

More than 2.5 Million device-based **ISS** are used within the EEA and Switzerland for:

- ✓ drinking and pool water treatment
- ✓ water softening and cooling water treatment

Advantages of device-based **ISS**:

→ No need for transportation of “typical” hazardous biocidal products

→ No storage of hazardous substances/products

→ No quality deterioration by improper handling and storage

→ Reduced risks for humans and environment by generation of active substance in closed systems

Device-based in situ systems – Needs of the Market

→ Improvement of biocide quality by immediate consumption of generated active substances in best available quality.

→ Customers such as municipalities (e.g. swimming pool operators, potable water supply entities) have been demanding and relying on in-situ generated biocides for decades.

→ The requirements for a safe and reliable operation of ISS devices are described in widely acknowledged and applied European and national guidelines and standards.

Regulatory aspects for product authorisation of device-based ISS

- In the Regulation (EU) No. 528/2012 (“BPR”) no obligation exists to authorise devices.
- Devices are neither biocidal products nor biocidal active substances.
- Requirements for device-based ISS according to article 19(1)(c) BPR must be further specified.
- However, device manufacturers:
  - ✓ wish to ensure the availability of *in situ* technology on the market and are thus
  - ✓ willing to taking over the role as authorisations holders and commit themselves to product authorisation

Need for clarification & guidance

- One active substance dossier for an **ISS** (“Active chlorine generated from sodium chloride by electrolysis”) is presently under review with an expected BPC opinion in early 2018.
- First authorisation applications may already be submitted to MSCAs as soon as there is a positive BPC opinion in 2018.
- Need for **<u>immediate clarification on:</u>**
  - ✓ data guidance for device-based ISS
  - ✓ authorisation procedures of device-based ISS
  - ✓ ISS devices already on market
- Without further guidance on data requirements besides those provided for in the BPR significant resources will be bound on both the eCA’s and industry's side.

The way forward…

A generic approach as a basic concept for product authorisation of device-based ISS

Generic approach - Our proposal

- Identify worst case conditions considering existing regulations and standards for the precursor sources, devices and use scenarios of application and use.
- Cluster *in situ* systems by implementing an integrated, generic approach.
- Respect the data requirements as laid down in Annex III and Annex VI of the BPR based on available information and generate additional data when not yet available or if they cannot be derived.
- Demonstrate for a group of device-based ISS different precursor sources, different water qualities and different devices that the *in situ* generated active substance quality is within pre-defined specifications the same or very comparable.
- Consider type and extent of disinfection by-products (DBPs) formed or other substances of concern.

Conclusions

A generic approach is the solution

- The overall objective is to determine a reasonable worst case scenario on the basis of applicable currently existing regulations and standards and to deliver and/or produce relevant data in accordance with the BPR provisions for this integrated, generic approach.
- By demonstrating that different sources of precursors/devices can be used to generate the same active substance on the basis of pre-defined worst case conditions/systems for different applications this will allow a clustering of exposure scenarios for human health and environment.
- From a regulatory point of view the implementation of the proposed generic approach could be done following different authorisation strategies.
- Eventually, a generic approach ensures the continuation of ISS-based disinfection at feasible effort for authorities and manufacturers.

All comments and remarks to our proposal are very welcome.

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