Application of Regulation (EU) No 528/2012 ("BPR") to disinfectant 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)

August 2017

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AE and ECA are very thankful for the intense and constructive support by the consultants. However the full responsibility for the content of this proposal lies solely in the responsibility of Aqua Europa and ECA Consortium.

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Executive Summary

In a first meeting in this regard on 23 May 2016, the EU Commission suggested to Aqua Europa's representatives, to prepare a proposal for the product authorization of in situ systems. Following an initial position paper of 6 March 2017[1] and as a result of a meeting with the EU Commission, DG Health and Food Safety, on 20 June 2017, manufacturers of devices used for the *in situ* generation of active substances were advised to further develop their proposal for structuring the future authorisation procedure for biocidal products relating to the *in situ* generation of active substances by use of devices in PTs 1 to 5 and probably in PTs 11 and 12.

Against this background, the proposal outlined herein contributes to further discussions and consultations on CA and ECHA level and could possibly also be included in the existing recommendation on data requirements for *in situ* generated active substances with a view to future product authorisation (PA) procedures or upcoming guidance documents.

Device manufacturers are aware of the fact that no obligation exists in Regulation (EU) No. 528/2012 ("BPR") to authorise devices. Nevertheless it has been clarified[2] that device manufacturers also can be authorisation holders, at least optionally.

Device manufacturers understand that data requirements in connection with the authorisation of biocidal products *inter alia* relate to the identity of the biocidal product, its intended uses and related exposure. Device manufacturers are, therefore, concerned that the application of already developed thoughts and ideas regarding data requirements for biocidal product authorisation will result in a scenario that requires the provision of details regarding specific precursors, individual devices and potential conditions of use with the effect that, in general, data for each individual device in use or placed on the market might be necessary.

Due to the variety and high number of devices placed on the market, a pragmatic, practical and integrated authorisation approach is essential to meet the requirements of the BPR to ensure efficacy, environmental safety and consumer health on the one hand, and to enable

[1] See Aqua Europa Proposal for designing the procedure for the authorisation of biocidal products for in-situ water treatment systems, as of 6th March 2017

[2] See CA-March15-Doc.5.1-Final, revised on 23 June 2015

market actors (including users of in situ systems) in general and device manufacturers in particular to comply with corresponding requirements of the BPR on the other hand.

The aim of this proposal for product authorisation of active substances generated *in situ* by devices is to provide a way forward with special focus on a generic approach: The device manufacturers propose to refer to existing legal obligations, regulations and standards existing or to be developed for precursor qualities, devices and use conditions to define the data requirements for applications for biocidal product authorisations on a worst case basis approach – comparable to the evaluation procedure of non *in situ* based biocidal products.

By clustering precursors, devices and use conditions on basis of applicable regulations and standards a generic approach would both save time and resources within the eCAs as well as in the industry whilst making no compromise on environmental or human safety. Based on applicable regulations and standards worst case conditions could be defined to assess and to ensure that the prerequisites of the BPR are met regardless of the specific use case, as long as and as far as precursor, device and use conditions comply with the details specified by applicable regulations and standards considered for the identification of worst case scenarios. Even though commonly acknowledged standards will be referred to, it is recognized that existing data will have to be extended and the generation of additional new data to support and underline worst case scenarios developed, on basis of these applied standards, following basically the requirements of Annex III of the BPR.

1. Background and purpose of this document

On the advice of the EU Commission representatives of *in situ* device manufacturers prepared a position paper titled “Proposal for designing the procedure for the authorisation of biocidal products for *in situ* water treatment systems” of 6 March 2017. This position paper outlines the perspectives and challenges faced currently by numerous device-manufacturing companies as well as operators of *in situ* generators - devices in operation for the *in situ* generation of biocidal active substances mainly intended for the treatment of drinking and swimming pool water (hereinafter referred to as “**devices**”). Device-manufacturing companies are presently investigating the most feasible options for product authorisation to ensure that this significant industry can continue providing their systems to the European market and thereby complying with the provisions of Regulation (EU) No. 528/2012 (“**BPR**”).

By now, more than 2.5 Million device based in-situ-systems used for treatment of drinking water, pool water, water softening and cooling water[3] are providing very valuable services for the health of consumers and the protection of the environment in the EEA and in Switzerland. Device based In-situ systems are reducing the transportation and storage of hazardous substances, are avoiding risks of inadequate handling and usage of disinfectants by generating only the amount of active substances needed in the moment and at the point of use. They avoid the deterioration of the quality of the active substances by improper handling and storage. And they avoid the risks for humans and the environment by being generated and used in closed technical systems.

When the BPR came into force, on 1 September 2013, active substances generated *in situ* were, for the very first time, now within the scope of application of European biocides regulations. Since then much work has been done by ECHA, MSCAs and other stakeholders in order to define and classify existing precursor / active substance combinations (i.e. in-situ

[3] More than 1.5 Mio in-situ-systems are used for the treatment of drinking water and for the hygienic cleaning of raisin in water softeners. See article: "Biozidrecht und Wasseraufbereitung – Lösungen für In-situ-Anlagen?" by Gotthard Graß, Karl Morschhäuser and Adrian Uhlenbroch (figawa e.V.), published April 2014, gwf-Wasser|Abwasser. In addition more than 5 Million public, semipublic and private pools are in use in the European Economic Area (EEA) and Switzerland. Experts from the European Union of Swimming Pool and Spa Associations (EUSA) estimate that around 20 % of these pools are using in situ generated active substances as disinfectants.

systems "**ISS**"[4]). The document CA-March15-Doc.5.1-Final[5] was established as a result of the responses received on a questionnaire sent out by the EU Commission in January 2014 in order to collect information on all ISS already on the EU market. As a result, ISS were re-defined to establish a clear connection between the *in situ* generated active substances and the precursor(s) they are generated from. In parallel, applicants had the opportunity to include all existing ISS into the review programme by notifying these systems to the EU Commission by 27 April 2016 at the latest in a post-notification procedure. To this end various ISS relating to the use of devices have been notified according to the list of compliant notifications published by ECHA.[6]

Nevertheless, even though *in situ* generated substances are now explicitly mentioned in the BPR, numerous uncertainties, in particular with regard to the specific data requirements for future product authorisation procedures remain.

In this respect we acknowledge the efforts of the responsible European bodies (ECHA, EU Commission, eCAs) to close the gap of an as yet lacking guidance on *in situ* system by the recent release of the *Recommendation of the BPC Working Groups* (APCP, EFF, Tox, Env) entitled "*In situ* generated active substances – Risk assessment and implications on data requirements for active substances generated *in situ* and their precursors"[7]. This recommendation paper of the BPC WGs focuses on clarifying the principles for information requirements and risk assessment of the precursors of *in situ* generated active substances but also sheds some light on the information requirements for the active substances generated. This recommendation therefore was used as a basis to prepare this proposal.

Insofar as applications for active substance approval of ISS have already been submitted and are currently validated/evaluated or, where necessary, compliant notifications have been submitted for the redefined ISS, related biocidal products can continue to be placed on the market and to be used in accordance with the transitional provisions laid down in Articles 89 (3) and 93 of the BPR.

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[4] See CA-March15-Doc.5.1-Final, revised on 23 June 2015
[5] Ibid.
[6] See the list of compliant notifications
[7] Recommendation of the BPC Working Groups - In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors,

With respect to upcoming authorisation procedures it follows already from Article 17 BPR that a product authorisation does not have to be applied for individually by every user. It is sufficient that an authorisation is being granted for the biocidal product in question and that the product is being used as specified in the authorisation. In particular, producers of devices are not legally obliged to apply for product authorisation. Device manufacturers are however willing to take on this task to ensure availability of *in situ* technology on the market by becoming authorisations holders.

To date no active substance approval has been granted for an ISS although numerous systems are already subject of active substance approval procedures[8]. However, at least one active substance dossier for ISS is presently under review with an expected BPC opinion date early in 2018. It is to be expected that the missing guidance on how to handle *in situ* generated disinfectants based on devices is likely to lead to confusion and derangement in the following product authorisation process, as no common approach is available for the industry to follow.

Without further immediate clarification regarding the data requirements in connection with upcoming authorisation procedures relating to ISS, significant resources will be bound on both the eCA and industry side as a consequence since large amounts of data will need to be generated in individual proceedings. This could furthermore result in the elimination of thousands of *in situ* systems currently placed on the market in accordance with applicable legal and technical requirements, since small or medium-sized enterprises (SMEs) will no longer be able to support the possibly lengthy data requirements, leading to possible high impact on both, the environment and public health and safety.

In this context, considering the lack of sufficient guidance and due to the fact that market actors may submit applications for product authorisation as soon as the decision to approve the corresponding ISS is adopted, a definition of a realistic and feasible concept on the conditions and requirements for the authorisation of device-based ISS needs to be developed with high priority. This proposal shall contribute thereto.

[8] See the list "in situ generated biocidal active substances redefined"

2. Understanding of terms

The abbreviation "**ISS**" designates the specific active substance system corresponding to the redefinition in CA-March15-Doc.5.1-Final, revised on 23 June 2015, i.e. the combination of precursor and active substance, possibly supplemented by references to the process (e.g. electrolysis, acidification).

Separately from this, the term "**device**" designates the entirety of equipment or plant technology used to generate the active substances from precursors and/or to generate biocidal products from ubiquitous raw materials and which as such is not or cannot be the subject of an authorisation decision under biocides law (see Article 17 BPR).

Unless stated otherwise terms used in this proposal shall have the meaning according to the definitions in Article 3(1) BPR and in harmony with the understanding of terms according to the CA documents referred to.

3. Requirements under BPR according to previously finalised CA documents

According to Article 17(1) BPR, only biocidal products within the meaning of Article 3(1)(a) BPR are subject to an authorisation obligation. Authorisation can thus only refer, according to Article 17(3) BPR, to a biocidal product or a biocidal product family.

In light of this, CA-March15-Doc.5.1-Final[9] clarified the following:

- The marketability and/or usability of precursors to be marketed with a biocidal intended purpose requires both a corresponding active substance approval and a product authorisation based upon it;
- In principle, every interested market participant and/or user can conduct active substance approval and product authorisation procedures relating to specific ISS;
- For ISS based on ubiquitous raw materials or on precursors marketed without a biocidal intended purpose, in any case the operator of the corresponding device will have to ensure adequate product authorisation unless other actors in the supply chain (such as producers of precursors or device manufacturers) take on this task;
- Harmonised technical standards (e.g. European standards (EN)) come into question for determining ISS with regard to the active substance approval procedure. They can also be used in assessing technical equivalency to avoid potential systemic distortions between active substance approval and subsequent product authorisation.[10]

[9] See CA-March15-Doc.5.1-Final, revised on 23 June 2015.
[10] Ibid.

4. Proposal for a generic approach with a view to product authorisation relating to ISS

4.1. General considerations on the generic approach

The inclusion of ISS and their use in the scope of the BPR is only partly acknowledged in the procedural provisions of the regulation. The usual understanding of a two-part evaluation process staggered over time consisting of active substance approval and product authorisation creates specific issues for ISS which need to be clarified.

Unlike ordinary biocidal products which normally contain one or more previously approved active substances, ISS are characterised by the fact that the biocidal products subject to authorisation are not biocidal active themselves as they contain no active substance (as with precursors, see Article 3(1)(a), 1st indent BPR), or are in principle identical to the previously approved active substance (as with ISS with no tradable precursor, see Article 3(1)(a), 2nd indent BPR).

The BPR also determines for ISS that solely the active substance approval and product authorisation are the prerequisites for the marketability and usability of the biocidal product to be assessed. The requirements for ISS should, thus, neither be stricter nor more lenient than those for other ordinary biocidal products. Thus, the interactions envisaged between active substance approval and product authorisation in the BPR shall be properly implemented for ISS, too.

At the same time it should be guaranteed for ISS that product authorisations ensure the general marketability and usability of the relevant biocidal products (cf. Article 17(1)) BPR). This makes it necessary to create a procedure which enables safe use of biocidal products, either generated *in situ* or used for *in situ* generation, in a large number of individual applications in compliance with the objectives of the BPR. To that end, the approach already supported in CA-March15-Doc.5.1-Final is welcomed from the perspective of the device-manufacturing industry.[11]

[11] See CA-March15-Doc.5.1-Final, revised on 23 June 2015. As stated therein on page 4: "It is acknowledged that a comparison of the chemical composition and hazard profile of the in situ generated active substances would be technically difficult, if not impossible, to achieve, as it may in particular be challenging to establish a reference source. It might however be possible to establish technical specifications or to refer to existing standards, such as CEN standards. These technical specifications could be established either for the active substance itself or its

According to the recommendation of the BPC Working Groups on *in situ* generated active substances[12], the biocidal products subject to authorisation are:

1) The substances and/or mixtures generating the active substance. If active substances produced by using ISS are also available on the market as industrially produced active substances (e.g. active chlorine), assessment parameters for the same individual applications should be uniform within the objectives framework set by the BPR.
2) The active substance generated from substances or mixtures that cannot themselves be authorised as biocidal products (e.g. ozone generated from ambient air, active chlorine generated from seawater). As far as the active substance and the biocidal product are to be considered equivalent (as with ISS without a tradable precursor, see Article 3(1)(a), 2nd indent BPR), there are ultimately no further authorisation requirements deemed necessary as a safe use has already been proven as part of the active substance approval. A list of these systems is provided for in Annex I of CA document "CA-March15-Doc.5.1-Final, revised on 23 June 2015.

In this context it needs to be noted that the recommendation of ECHA focuses primarily on typical chemical systems for the *in situ* generation of actives as mentioned in (1) above. In the context of device based systems no guidance and/or specific considerations are available as addressed in (2) above.

As a consequence, ISS and corresponding biocidal products are subject to specific considerations, depending on precursor sources and devices used. In this respect, the requirements for providing broader evidence according to Article 19(1)(c) BPR must be further specified. It should be acknowledged that the *in situ* generation, while observing certain fixed parameters with reference to established legal obligations, regulations and (harmonised) technical standards, is therefore recognized to be one and the same production process.
Based on existing regulations and standards, for the precursor sources as well as the devices and use cases, worst case conditions can be identified which would enable a clustering of all systems and implementation of the integrated, generic approach. By doing so it can be assured

precursors, as appropriate, at the time of the substance approval. It will then have to be ensured and demonstrated at the time of product authorisation that the precursors or the active substances, as appropriate, meet the agreed specifications."

[12] See Recommendation of the BPC Working Groups - In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors

that differences in precursor sources, as well as devices used, are unlikely to have an impact on the quality of the *in situ* generated active substance if the given device parameters and conditions are respected.

The validity of this approach and the impact of different input parameters will have to be investigated by performing pilot trials considering worst case conditions in terms of choice of the precursor source and water quality. This should be done creating a core data set for worst case scenarios, which should be defined on the basis of details pointed out in this proposal.

A possible worst case scenario approach could include the choice of a designated salt quality, as defined by a technical standard, to showcase the worst case for the different salt qualities currently on the market/ used for different applications.

- For a group of ISS it will be demonstrated that despite different sources of precursor, different water qualities and different devices the result of the *in situ* generated active is the same, within pre-defined specifications.
- On the basis of this demonstration worst case exposures for human health and environment can be justified and can represent a group of ISS.
- By using already standardised and regulated qualities of precursor, water and device as default values in descriptions of exposure scenario used for the risk assessment maximum ranges for disinfection by-products (DBPs)[13] or other substances of concern can be derived.
- Data missing that cannot be derived will be generated on a similar basis as for non in-situ biocidal products.

For the implementation of the proposed integrated, generic approach for product authorisation (PA) of biocidal products relating to ISS and in order to avoid numerous individual biocidal product authorisations, existing regulations and standards, serve as the basis. Please refer to Annex I for more comprehensive information on existing standards for precursors and devices as well as further technical standards.

[13] *ECHA, Volume V, Guidance on Disinfection By-Products* (Version 1.0, January 2017)

Where standards are missing, these could be established in a reasonable period of time[14]. If necessary, development of relevant standards could already be initiated in connection with findings and results of the ISS approval procedures.

In addition, making use of existing standards to identify reasonable worst case scenarios (Article 19(2)(a) BPR) would also ensure that requirements to fit these standards are on the highest levels over the whole of Europe. It is imperative that any worst case approach with a view to product authorisation under the BPR following an integrated, generic registration strategy still need to fulfil the data requirements as laid down in the Annex III of the BPR.

Linking the authorisation procedure with mandatory pre-established requirements of legal and technical standards enables the public concerned and the competent authorities to precisely monitor compliance with use conditions. Also, active participation by the Member States' authorities responsible for implementing the BPR and/or ECHA or the EU Commission on the testing and refinement of the relevant technical standards would then be expedient in order to contribute the resulting know-how from the authorisation procedures to the further development of the generally accepted state of the art.

4.2. Example based on sodium chloride (NaCl) generating active chlorine *in situ*

For a better illustration and understanding on the generic approach, the *in situ* generation of active chlorine from sodium chloride by electrolysis is used as an example which can be applicable to other device-based in *situ* generated active substances. For the *in situ* generation of ozone from ambient air these considerations need to be adapted as there is no precursor and, thus, no biocidal product, made available on the market. In this particular case, *in situ* generated ozone represents both the active substance and the biocidal product[15]. In general the proposed approach would follow legal requirements, as guidelines and requirements, outlined and published by ECHA and competent authorities.

The main aspects to be taken into consideration when establishing a concept for the authorisation of ISS can be based on the recommendation of the BPC Working Groups on in

[14] The procedures and timelines for the development of CEN Standards are described in the document CEN/CENELEC Internal Regulations Part 2, Common Rules For Standardization Work, February 2017

[15] See CA-March15-Doc.5.1-Final, revised on 23 June 2015.

situ generated active substances[16]. With a view to the product authorisation of device-based in situ systems, four groups of main components in these systems have been identified:

I. Device/System
   - Generation process including the conditions and their variations

II. Precursor
   - Information on the precursors
   - Maximum applied concentration of the precursors for generation

III. Water quality
   - Definition of worst case test water

IV. Technical active substance generated *in situ*
   - Information on technical active substance generated *in situ*
   - Concentrations of the constituents of the technical active substance generated *in situ* and their variations (normally measured or if not applicable calculated)
   - Quality control data of the technical active substance generated *in situ* as an indicator for the level of variation of the composition at different conditions: e.g. pH, temperature, dilution. Further conditions of the generation system and process might be required for product authorisation

To determine reasonable worst case scenarios against this background, applicable technical standards should be taken into consideration. For the ISS “Active chlorine generated from sodium chloride by electrolysis”, for example, standards are given in Annex I which can be used to identify a reasonable worst case scenario. These standards describe the currently used salt qualities for the generation of active chlorine based on NaCl by electrolysis by their composition, as well as their level of impurities.

4.3. Considerations on devices/ system

With a view to product authorisation, the definition of a base set of device-related parameters applicable to all different devices without any restrictions/limitations is required so that all types of devices in operation for ISS are covered by the generic product authorisation procedure.

[16] Recommendation of the BPC Working Groups - In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors

For this reason, specific considerations on the operation of the devices appear not to be necessary if it can be assured that the pre-defined device parameters for the *in situ* generation of the active substance are observed, acknowledging at the same time that the BPR is not intended to cover authorisations of devices.

In relation to devices used for the *in situ* generation of active substances, the following aspects are to be considered with a view to proposing a product authorisation procedure of device - based ISS:

1. Devices for the in situ generation of active substances already comply today with fixed parameters and operate according to standardised regulations (see Annex I**)** which should not be deviated from, even for the purpose of the identification of worst-case conditions for product authorisation.

2. It can be assumed that all devices operate according to a very comparable scheme if specific device parameters are maintained and kept under control. Therefore, specific considerations on the devices are not to be needed. Most importantly, the user of the device cannot change the pre-set device parameters or is instructed accordingly to that end.

The effects on target organisms, on the health of humans and animals and on the environment depend primarily on the characteristics of the water used/to be treated and the proper, standardized operation of the device rather than on the characteristics. As the major device parameters are preassigned, prohibiting the end user to change essential parameters, standardised operation within given limits can be assured. However, in order to be in line with the provisions of the BPR, the specific requirements laid down in the ECHA guidance on disinfectant needs to be respected to demonstrate sufficient efficacy of the *in situ* systems in the different intended applications in the concerned PTs.

4.4. Considerations on the precursor/biocidal product

In the recommendation of the BPC Working Groups on *in situ* generated active substances it is stated that precursors need to be described by their complete composition. “Depending on whether the precursor(s) can be regarded as so-called “commodity chemical(s)” the information requirements vary. Quality control data (QC data) or certificates of analysis (CoA)

are sufficient for commodity chemicals. Consequently, no analytical methods or analysis under GLP requirements for identification of the precursors need to be provided"[17].

According to the CA document CA-Sept15-Doc.4.3 – "Final „Compliance with and enforcement of Article 95 – The case of in situ generated active substances"[18], NaCl could be regarded as a precursor not supplied with the intention to generate an active substance for a biocidal use. If this be the case it will have an impact on the authorisation strategy for ISS as in such cases, no biocidal product consisting of, containing or generating a relevant substance is made available on the market.

If this definition applies to the NaCl precursor sources, which themselves are specified according to existing technical standards, these are not to be defined as biocidal products rather the in situ generated active substance will be regarded as both the biocidal product **and** the active substance, respectively. As a consequence, only a limited level of information on NaCl is expected to be required with a view to the hazard and risk assessment of the precursor. The technical standards[19] existing for these sources could be used as a basis for an adaptation of the data requirements for NaCl.

If NaCl is defined as a commodity chemical, the main efforts are, therefore, to be placed on the *in situ* generated active substance for hazard, exposure and risk assessments as well as considerations on technical equivalence.

It is noted that even if the "commodity chemical approach" applies for the precursor NaCl, the requirements/considerations on impurities/by-products as were mentioned in the recommendations of the BPC WGs on *in situ* generated active substances cannot significantly be deviated from.

The impact of the various sodium chloride sources, which themselves comply with corresponding European standards, on the active substance quality generated *in situ* is to be investigated by examining the specification of and the impurities contained in the various NaCl sources taking into account the provisions of the CLP regulation (Regulation (EC) No. 1272/2008). In contrast to typical "chemical" biocidal products which usually contain one or

[17] Recommendation of the BPC Working Groups - *In situ* generated active substances – Risk assessment and implications on data requirements for active substances generated *in situ* and their precursors
[18] CA-Sept15-Doc.4.3 – "Final „Compliance with and enforcement of Article 95 – The case of in situ generated active substances
[19] Please refer to Annex I

more approved active substances, ISS are characterised by the fact that the biocidal products (precursors) do in general not unfold biocidal activity themselves as they do not contain an active substance (as with precursors, see Article 3(1)(a), 1st indent BPR). However, the biocidal product could also be identical to a previously approved active substance which applies to those cases where no biocidal product is made available on the market. (see Article 3(1)(a), 2nd indent BPR).

4.5. Considerations on water quality

In order to prove that irrespective of the device all systems operate in a comparable manner, it appears both appropriate and essential to determine the necessary parameters by defining a worst case test water as a basis for the provision of data (in the relevant PT)[20] in the first instance. For the purposes of the product authorisation procedure a test water should be defined which also complies with the stipulations of Article 19(2) of the BPR in order to provide the required proofs according to Article 19(1)(b) BPR. As one of the existing examples for a worst case scenario DIN 19643 could be mentioned, which not only defines a scenario for a highly contaminated water but also sets up clear rules for the efficacy of the disinfectant and additional parameters.[21]

For drinking water an approach for defining and testing the efficacy of disinfectants is developed and used by the German Umweltbundesamt.[22]

Appropriate evaluation and testing strategies could be developed by combining existing legal requirements, standards and testing procedures for disinfectants and disinfecting processes and existing data from those tests with evaluation and testing models, set up by the BPR and existing guidance documents.

[20] The ECHA Guidance on Disinfection By-Products contains the corresponding considerations
[21] See Bekanntmachung des Umweltbundesamtes: Hygieneanforderungen an Bäder und deren Überwachung, 2014
[22] See Umweltbundesamt: Quantitative Bestimmung der Wirksamkeit von Stoffen zur Desinfektion in der Trinkwasseraufbereitung, 2010

4.6. Active substance generated *in situ*

The requirements for the technical active substance generated *in situ* have been referred to within the most recent recommendations of the BPC Working Groups on *in situ* generated active substances. According to these recommendations the following definitions and considerations apply:

- Technical active substance generated *in situ* comprises the pure active substance, reaction by-products, unreacted precursors and other impurities (e.g. contaminants from precursors).
- The *in situ* generated active substance refers to the pure active substance generated, and does not include unreacted precursors, reaction by-products and impurities (e.g. contaminants from precursors). If the *in situ* generated pure active substance exists also as an active substance on its own, the data requirements on the *in situ* generated active substance for product authorisation should be based on the data available on the active substance. The assessment of the pure active substance can, therefore, be accomplished by making reference via a letter of access (LoA) for instance to the original active substance dossier. This is of particular importance if the precursor NaCl is defined as a commodity chemical in which case the *in situ* generated active substance rather than the precursors NaCl is to be dealt with as the biocidal product.
- The pure active substance may consist of multiple active chemical species. If additives and/or unreacted precursors are active substances on their own right, these additives and/or unreacted precursors will be regarded as part of the pure active substance; in such cases unreacted precursors are not impurities.
- Impurities are the non-active part of the technical active substance generated *in situ*. They originate from the (non-active) precursors or are the result of (unwanted) secondary or incomplete reactions during *in situ* generation.
- Unreacted precursor(s) and reaction by-products are also regarded as impurities. Reaction by-products may also be formed during *in situ* generation and are considered as impurities as they are not contributing to the efficacy. Reaction by-products originate from intended reaction(s) of the precursors by complete or incomplete reactions.

During the approval procedure of the *in situ* generated active substances, unreacted precursors, reaction by-products and impurities (e.g. contaminants from precursors) might not have been considered in sufficient detail.

As a result and in order to identify possibly unreacted precursors and impurities these particular elements are definitely to be considered during the biocidal product authorisation process requiring specific information on e.g. reaction kinetics/time dependency and precursor stoichiometry for the *in situ* generation of the active substance.

5. Outlook and challenges for future product authorisations

In contrast to other systems where the active substance is generated *in situ* by the chemical reaction of one or more precursors, no active substance approval has been granted to date for a device-based ISS[23]. Irrespective of the ongoing active substance approval procedures for device-based ISS, the stakeholders concerned were advised to already take the first binding steps with regards to the future product authorisation of their systems for the *in situ* generation of e.g. active chlorine, active bromine and ozone, respectively.

The overall objective is to determine a reasonable worst case scenario on basis of applicable regulations and standards and provide relevant data in accordance with the BPR for this scenario. Demonstrating that different sources of precursor can be used to generate the same active, despite different water qualities and devices, on the basis of worst case precursor for different applications will allow clustering of ISS in terms of exposure scenarios for human health and environment.

From the regulatory point of view the implementation of the proposed generic approach could be done following different authorisation strategies. Nevertheless, doing so by applying the Biocidal Product Family ("BPF") concept, would seem like the most promising and resource saving course of action. Considerations have been internally discussed and investigated accordingly.

With a view to the integrated (generic) authorisation approach proposed herein and in order to avoid an extensive number of individual product authorisations which may neither manageable for the MSCAs nor the industry, the formation of consortia among stakeholders is recommended in order for the concerned companies to remain on the market.

Most importantly, further clarification of the content and the requirements of the product authorisation procedure is, thus, necessary both for producers of precursors and for operators of devices to ensure compliance with the BPR for device-based ISS. In this respect, a pragmatic and feasible authorisation strategy has been investigated taking into account the multitude of devices on the market, the range of biocidal applications they are used for and, more importantly, the user groups concerned.

[23] See the Biocidal Products Committee opinions on active substance approval

Considerations on the identity of the authorisation holder are of particular importance and it appears reasonable that both precursor suppliers and producers of devices could take over the role as authorisation holders instead of operators/users of devices which could be operators of public swimming pools but also private households for instance.

Annex I: Already existing standards which possibly could be used for defining worst case scenarios

PT 1 - 5:

- **EN 937** Chemicals used for treatment of water intended for human consumption. Chlorine
- **EN 15363** Chemicals used for treatment of swimming pool water - Chlorine
- **EN 14805** Chemicals used for treatment of water intended for human consumption. Sodium chloride for on site electrochlorination using non-membrane technology
- **EN 16370** Chemicals used for treatment of water intended for human consumption. Sodium chloride for on site electrochlorination using membrane cells
- **EN 16401** Chemicals used for treatment of swimming pool water. Sodium chloride used for electrochlorinator systems

PT 11, 12:

- **EN 937** Chemicals used for treatment of water intended for human consumption - Chlorine
- **EN 15363** Chemicals used for treatment of swimming pool water - Chlorine
- **EN 14805** Chemicals used for treatment of water intended for human consumption. Sodium chloride for on site electrochlorination using non-membrane technology
- **EN 16370** Chemicals used for treatment of water intended for human consumption. Sodium chloride for on site electrochlorination using membrane cells;
- **EN 16401** Chemicals used for treatment of swimming pool water. Sodium chloride used for electrochlorinator systems

Devices

- **DIN 19606:2006-06** Norm chlorine gas devices for water treatment – construction and operation
  (Norm Chlorgasdosieranlagen zur Wasseraufbereitung - Anlagenaufbau und Betrieb)
- **DIN 19643-2:2012-11** Treatment of pool water
  (Aufbereitung von Schwimm- und Badebeckenwasser)
- **DIN 19633:1986-01** Norm ion exchanger for water treatment: technical terms of supply
  (Norm Ionenaustauscher zur Wasseraufbereitung; Technische Lieferbedingungen)

Annex II: Product authorisation for ISS - Considerations on specification of precursors and Technical Equivalence (TE)

In the most recently issued Recommendation of the BPC Working Groups on *in situ* generated active substances, the following is stated regarding TE:

- "The precursors need to be described by their complete composition. Depending on whether the precursor(s) can be regarded as so-called "commodity chemical(s)" the information requirements will vary. Quality control data (QC data) or certificates of analysis (CoA) are sufficient for commodity chemicals. Consequently, no analytical methods or analysis under GLP requirements for identification of the precursors need to be provided"[24].
- "The assessment of technical equivalence compares whether the hazard of a new source to the approved source(s) of the precursor(s) is equal or lower with regard to the chemical composition of the reference source(s). Therefore, the technical equivalence assessment of *in situ* generated substances has also to consider the compositions of the precursors and the reactions occurring in the generation process. That means information about the composition of the technical active substance is required. It should also be noted that different precursors generating the same pure active substance are regarded as different technical active substances. Further and detailed criteria will be elaborated in the specific BPR Guidance on applications for technical equivalence"[25].
- As an example, in the *in situ* generation of active chlorine generated from sodium chloride by electrolysis a worst case precursor salt ("reference salt") should be identified which is representative for all other salt qualities.
- If the salt quality assessed in the in situ dossier under review is defined as the reference source and if the NaCl precursors are regarded as the biocidal products, TE is to be demonstrated on the precursor level following the guidance and the tiered approach provided for by ECHA[26].
- Irrespective of its precursor function, if NaCl is defined as a commodity chemical, this type of precursor is not regarded to be the biocidal product. TE considerations will, therefore, be limited to the *in situ* generated active substance if this case applies.

[24] See CA-March15-Doc.5.1-Final, revised on 23 June 2015.
[25] Ibid.
[26] ECHA, Volume V, Guidance on applications for technical equivalence

Therefore, the LoA to the active chlorine dossier should be sufficient for the proof of technical equivalence of the pure active substance. However, with regards to the technical active ingredient, a TE assessment may have to be performed which is very likely related to the assessment of the potential (eco)toxicity of the *in situ* generated active chlorine.

Disinfection by-products (DBPs):

- Specific aspects may have to be observed in the product authorisation procedure regarding DBPs. This applies to by-products from the in-situ process, not reacted precursors and their retention in drinking or swimming pool water, for example, as well as to the disinfection by-products arising during disinfection and their retention in the water. PT- and application-specific DBPs deserve particular attention in the risk assessment process for which further guidance beyond that already available *Volume V, Guidance on Disinfection By-Products* (Version 1.0, January 2017)[27] will be needed.
- In this respect it is to be discussed whether or not DBPs other than those stated in the Drinking Water Directive (Directive 98/83/EC) need to be addressed as drinking water is intended for ingestion and represents, thus, a worst case in terms of DBPs. The main challenge in this respect consists in the identification of the type and nature of the DBPs formed depending on the intended application and the water used in the *in situ* generation process.

Devices used:

- It is assumed that all ISS operate according to a very comparable scheme if specific device parameters are maintained and kept constant. Considering available standardised regulations for the operation of such devices specific considerations are not deemed necessary. This assumption may be demonstrated by providing the results of key experiments such as using a test water, one specified NaCl source and different devices/apparatus.
- Key parameters could be active chlorine quality/concentrations and impurities formed (identity of impurities is still to be defined).
- Device Manufacturers are actively participating in the improvement of existing and development of further standardisation procedures on both European and national levels. The overall aim of their participation is to improve and ensure the quality of

[27] *ECHA, Volume V, Guidance on Disinfection By-Products* (Version 1.0, January 2017)

devices, improve efficacy and to reduce risks of the generated substances to both the environment and human health. These standards and regulations are defined on a national and European level, involving stakeholders not only from industry, but competent authorities also. These standards are based on basic requirements set up by European legislation which is mandated by the EU-Commission to CEN[28].

[28] The procedures and timelines for the development of Cen Standards are described in the following document: https://boss.cen.eu/ref/IR2_E.pdf