

# Implementation of the EU Biocidal Products Regulation No. 528/2012 when working with biocides produced in-situ in water purification and treatment operations

## Guidance notes 01/2017

### Status report for manufacturers and sellers of in-situ devices

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The EU Biocidal Products Regulation 528/2012 (BPR), as well as numerous subsequent supplementary provisions, provide uniform rules governing the marketing and use of active biocidal substances and biocidal products throughout the European Economic Area. The principle which applies is that only approved biocidal products may be marketed and used. Unlike the Biocidal Products Directive which applied previously, the BPR also covers the manufacture of active biocidal substances at the location where they are used – so-called in-situ manufacture – as well as the use of disinfectants for drinking water and swimming/bathing pool water hygiene. From a legal viewpoint, in line with the restructuring carried out by the responsible Competent Authorities ("CAs"), a distinction must be made between the equipment used, i.e. the **in-situ devices**, and the so-called **in-situ systems**, i.e. the active substance system comprising the active substance that is produced (e.g. "active chlorine"), the precursor that is used (e.g. salt), and the production process (e.g. electrolysis).

In light of the above, leading German and European associations of manufacturers and operators of in-situ systems in the drinking water and swimming/bathing pool water hygiene field joined together to form an umbrella group in March 2015, and they also established a common steering committee, which was tasked with clarifying the numerous unresolved issues. These guidance notes summarise the most important issues that have been clarified by the umbrella group over the last two years, as well as the course of action that manufacturers and operators of in-situ systems in the water hygiene sector are planning to take in future.

## Current position

1. From a purely legal standpoint, the BPR does not impose any additional obligations on manufacturers/suppliers that only supply water purification and treatment systems to the EU market.<sup>1</sup> Nevertheless, all manufacturers/suppliers of in-situ devices should study the BPR requirements closely and decide whether they wish to participate in the current active substance approval procedures as well as the future product approval procedures, and if so on what basis.

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<sup>1</sup> The EU Commission already confirmed, that device manufacturers – in addition to precursor suppliers (company placing a product on the market) and system operators (users) respectively – are allowed but not obliged to take part in the procedures according to the BPR.

2. A legal duty applies to suppliers of precursors, i.e. substances such as salt, which are specifically designed for use in in-situ systems (i.e. marketed on the basis of their "intended use"). These suppliers currently ensure that they can continue to market the precursors, and the active substances produced from them, by participating in the active substance approval procedure and being registered in the so-called [Article 95 list](#). For this, a supplier requires an access authorisation ("Letter of Access or LoA") to an existing active substance dossier or to an active substance dossier submitted by themselves. This is explained in more detail in the 1<sup>st</sup> Figawa guidance note, which can be found at <http://www.biozid-isg.de/arbeitsergebnisse>.
3. In the case of disinfection processes that do **not involve the use of a precursor explicitly specified by the supplier for the production of a biocidal active substance** (e.g. ozone that is produced in situ from air, water or pure oxygen and is not specifically marketed for biocidal use), **responsibility is transferred in practice to the device manufacturer**, since neither the system operator nor any other market participant is able to undertake the required procedures, nor do they have any economic interest in doing so. The situation is therefore much less clear in relation to procedures where no commercially traded precursors – or only precursors not specifically marketed for biocidal use – are used. In such cases, a different course of action may be needed than for that which applies to commercially traded precursors that are specifically marketed for biocidal use. In these cases in particular, it is advisable for the respective device manufacturer to provide regular assistance with the active substance approval procedure (rather than just obtaining an LoA).
4. **If the device manufacturer buys or sells salt or other precursors, they should ensure that at least one party in their (own) supply chain participates in the corresponding approval procedure.** An overview of the suppliers of materials and precursors who currently participate in the active substance approval procedure is provided in the ECHA [Article 95 list](#).
5. A wide range of so-called in-situ systems are currently going through the **active substance approval procedure**. They include all of the procedures for treating drinking and swimming/bathing pool water that have been approved in Germany. The use of in-situ systems that are not undergoing an approval procedure will no longer be permitted once the currently valid transitional rules expire in the course of 2017.

These procedures investigate the fundamental effectiveness of the active substance as well as its toxicological and eco-toxicological properties, but also properties of the precursor. It is also important that these approval procedures are carried out for the correct respective field of use, i.e. the correct product type (PT). [An overview of the PTs is provided on the ECHA website, among other places](#), or it can be found in Annex V to the BPR. The in-situ systems specified by the figawa members are listed in the [01/2016 guidance notes](#); there is also an [overview of the systems that were retrospectively notified up to 27<sup>th</sup> April 2016](#). If the combination of precursor and active substance used or the corresponding field of use is not included in this list, please get in touch with the umbrella group. The first active

substance approvals for in-situ systems are not expected to be issued until the start of 2018 at the earliest.

## Planned further course of action

6. The publication of the active substance approval in the form of an EU Commission implementing regulation in the Official Journal of the EU marks the start of a period lasting roughly two years in which submitting an application for Phase 2 of the procedure is permitted: this is known as **product approval**. The umbrella group is currently clarifying whether this procedure is of any relevance to the device manufacturers, and if so, then to what extent.

It is however already clear that in relation to systems where no commercially traded precursors are used – or only precursors not specifically designed for biocidal use (intended use) – the device manufacturers will in practice also be forced to obtain product approval.

7. The steering committee has been requested by the EU Commission to put forward an appropriate proposal for cross-system regulation of the product approval procedure for in-situ systems.
8. The proposal currently favoured by the steering committee involves **submitting an overarching product approval application covering each in-situ system as well as the corresponding biocidal product and each field of use specified in the BPR, if necessary based on the creation of families of biocidal products; the application should be based on the corresponding legal rules, standards and policies for the drinking and swimming/bathing pool water sector**, and it should also cover all **corresponding existing and new devices and apply irrespective of the usage environment**. The steering committee is fleshing out this proposal as a matter of urgency. This could result in a jointly organised and financed approval procedure for all manufacturers of in-situ devices who use the same in-situ system.
9. Once the internal work has been completed, from February 2017 onwards the umbrella group will guide this proposal (via AQUA EUROPA) through the necessary consultation processes with the European Chemicals Agency (ECHA) and the responsible CAs at national and European level, as stipulated by the European Commission.
10. The steering committee believes that significant procedural risks would result from an approval procedure determined exclusively by suppliers of precursors that are specifically designed for use in in-situ devices. Therefore in the steering committee's view, the approval procedure will have to take full account of issues relating to the method of operation and field of use of the in-situ devices as well as the applicability of the corresponding water industry rules etc. Particular importance will therefore be attached to ensuring that device manufacturers contribute their specialist expertise.

11. In parallel to the ongoing political discussions, the umbrella group and the steering committee are currently examining what the benefits of a joint approach to implement the approval procedures might be for manufacturers/suppliers of in-situ devices.

The steering committee currently assumes that the various consortia currently applying for active substance approval with regard to ozone that is produced in-situ will also seek to obtain a product approval.

In addition to the ongoing clarification of the legal framework for in-situ processes for manufacturing active chlorine or chlorine dioxide as a biocidal active substance for water purification and treatment – as outlined under points 7 to 9 – discussions are now being held with a consortium that is currently being set up for the purpose of securing product approval of the in-situ system "chlorine produced through the electrolysis of table salt".

12. Once the issues referred to under points 9 and 11 have been finalised – which is expected in the 2<sup>nd</sup> quarter of 2017 – the umbrella group will invite all of the interested companies to take part in the consultation and decision-making process. In addition, all the interested in-situ device manufacturing and sales companies will remain invited to take an active role in shaping the implementation of the BPR going forward.

## Your points of contact

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