



POSITION PAPER

Observations on the “Guidance on the Biocidal Products Regulation, Volume V, Guidance on Disinfection By-Products, DRAFT, version 1.0, October 2016” (Part 1 Human Health Risk Assessment and Part 2 Environmental Risk Assessment):

prepared by

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Preliminary Remark:

In general, this paper is based on and relates to the situation in Germany. Given, however, that Regulation (EU) No. 528/2012 is affecting the biocidal products industry throughout the EU it is likely that implications reflected in this Position Paper are – to a greater or lesser extent – comparable to potential effects in other EU Member States. In particular, not only the European swimming pool industry but also the drinking and waste water industry will face serious economic consequences due to increased regulatory requirements. Furthermore, users of biocidal products in these sectors are accustomed to have access to and rely on the supply of biocidal products manufactured in accordance with quality standards and national regulatory regimes compatible with European requirements. It cannot be guaranteed that imported products and materials will similarly conform with existing prerequisites.

To ensure hygiene in drinking water as well as water used in swimming and bathing pools, disinfection chemicals and disinfection procedures (biocides) are being used for decades in multiple ways. The entry into force of Regulation (EU) No. 528/2012 already led to severe challenges in connection with the disinfection of drinking water and swimming pool water due to the implementation of new requirements for biocidal products and their use within the EU, including the extension of the scope, inter alia due to the new definition of the term “biocidal product”, and newly implemented procedural requirements for all market actors. The new regime is capable of endangering the high level of public health provision established in Germany for decades ensuring the supply of clean drinking water and the protection against infection and contagion. Affected institutions particularly comprise hospitals, waterworks, local authority swimming pools, spas and therapeutic baths, and government-supported sea- and salt-water baths well-known for their therapeutic effects. The use of materials and procedures used to prevent the transmission of diseases through water will, in the best-case scenario, be significantly impeded, if not excluded in case compliance requirements lead to commercial unviability. In the end, this would result in putting public health at risk.

Introduction

- 1 On 1st September 2013, Regulation (EU) No. 528/2012 of the European Parliament and Council of 22nd May 2012 (hereinafter referred to as “**BPR**”) entered into force, which governs the the making available on the market and the use of biocidal products, replacing the Biocides Directive 98/8/EC (hereinafter referred to as “**BPD**”).
- 2 The scope of the BPR is broader than was the case under the BPD. The BPR explicitly governs the *use* of biocidal products, which includes "*all actions [...] including storage, handling, mixing and application [...]*"
- 3 The express aim of the BPR is to improve the free movement of biocidal products within the Community market. Biocidal products, however, should be consistent with high levels of public and environmental safety. For this purpose, the BPR embraces a wide range of products.
- 4 With view on water disinfection in swimming pools, the guidance document in discussion shall provide information on how to deal with disinfection by-products in connection with data requirements within administrative proceedings according to the BPR.
5. The current version of the draft guidance document gives rise to concern, which shall be detailed below (A to E).

Recommendations

- **Limitation of parameters to be measured and evaluated in connection with the assessment of disinfection by-products to parameters**
 - which are recognised throughout the EU,
 - which are established and controlled on the basis of existing and proven measurement methods,
 - for which a significant amount of reliable and conclusive data is available, and
 - which can be easily monitored in practice.
- **Initiation of a measurement campaign in a specified swimming pool model rather than in “referential” swimming pools, which, in fact, don’t exist.**

A Disinfection vs. halogenation

First thing to be noticed is that the document is titled “disinfection by-products” and aims at disinfection in general, while the text mentions halogenation only. We understand that public swimming pools, which are in the focus of the guidance document, are mainly disinfected by halogens and, thus, the disinfection by-products in discussion are mainly halogenation disinfection by-products. But neither is halogenation the only disinfection method for swimming pools, especially for private swimming pools (cf. EN 16713), nor are halogenated disinfection by-products the only disinfection by-products in discussion.

The document gives the misleading impression that other disinfection methods are either not in scope of the BPR and related data requirements or completely harmless. Further clarification should be added.

B The wide range of DBP's and its implication on the measurement and their interpretation

We acknowledge the thorough elaboration of the guidance document, which is well researched and considers the fact that the range of DBP's is very broad and impossible to be measured in its entire spectrum. It was recognized that only little data on the impact of each and every disinfection by-product is available. The conclusion to identify and focus on a small range of DBP's is therefore correct.

But we identify some problems associated with the proposed approach of carrying out a measurement campaign on a swimming pool “representative to all pools” in the market:

- a) Whereas some indicators chosen (e.g. chloral hydrate) are seldom measured, other indicators are known in academic research environments but are not evaluated on a broad scale in practice (e.g. haloacetonitriles or HAA's – which only few labs can measure at all). It is unclear, why these parameters were chosen as indicators, given their widely unknown impact on human health. It seems that they were chosen for the sole reason that some data (literature) is available, without envisaging the specific toxicological impact. At least the criteria for the selection of the parameter are not provided in the draft document. The scientific justification for the selection of parameters should, however, be included in the guidance document but also the focus on practicability of measurement campaigns should not be lost in this context.
- b) The disinfection of water with oxidizing biocides ensures the allocation of hygienically safe water. Depending on the quality of the water to be treated, DBP's can form in a certain range. There is no means of representing all type of waters, thus no evaluation or measurement can be representative for literally all waters/swimming pools.
 - It was recognized that “the type and amount of DBP's formed in swimming-pools depend on many variables, including the availability of organic

matter, the presence of (in)organic nitrogen compounds”, the concentration of suspended solids, the salinity of the water etc. It was also recognized that “due to this complexity it is very hard to predict beforehand which compounds will be formed in a specific situation and at which concentrations. The general rule for DBP minimization in context with disinfection is a thoroughly pretreatment of the water. Any new scientific information on DBP formation in swimming-pools can be taken into account”. Meanwhile 80 years of experience with chlorination of potable water proved that an effective pretreatment and best water quality at the moment of disinfectant addition ensure a very low level of disinfectant concentration and a minimized DBP formation (cf. German standard DIN 19643).

- The DBP's typically measured and evaluated in a swimming pool cycle are trihalomethanes (trichloromethane, bromodichloromethane, dibromochloromethane and tribromomethane), combined chlorine, chlorate & bromate and it is established throughout Europe, that these DBP's toxicologically represent the wide range of DBP's in swimming pools. They are typically measured in most public swimming pools and a wide range of data is available. We are of the opinion that any DBP assessment in against the background of the BPR should focus on these parameters as indicators rather than establish new indicators for which little to no data is available. Otherwise evaluation of the toxicological and environmental impact of disinfection by-products will complicate without any guarantee or likelihood that improvements with respect to the protected interests according to Article 1 BPR can be achieved.
 - In the guidance documents in discussion, measurements of haloamines in the air are proposed: unfortunately water treatment methods do not correlate with by-products in the air (although it is of course correct that some by-products might be released), given that other factors such as ventilation & aeration, routing of the air flow etc. have a much greater impact on the concentration of DBP's in the air. Therefore, air measurement will not provide any reliable information, nor even any representative findings, and no improvements of the water treatment can be deducted from this data. This notwithstanding, it is, in addition, obvious that details vary between open air swimming pools and indoor pools, which is not yet sufficiently reflected in the draft document.
- c) There is no representative or standard pool type, which can represent all swimming pools in Europe, as there is no standard water treatment as implied in the documents in discussion. There is a wide range of influencing factors (e.g. temperature, pH, time of storage, filtration technique, kind of pollutants, organic matter in the water etc.) as well as swimming pool types (e.g. indoor, outdoor, big, small, deep, shallow, heavily loaded, little loaded, different fill water, different bathing cultures, different pool hydraulics, different weather

conditions etc.). Therefore, it is not possible to define a standard swimming pool representative to all swimming pools in the EU.

- d) There is no EU standard on swimming pool water treatment, on which measurements could be based.
- e) Also, it is not considered that the formation of DBP's is much more influenced by the utilization and operation of a facility rather than by the disinfection method or the chemical used to this end.

Nonetheless, the approach outlined in the draft document is generally appreciated. The question remains how the results shall be interpreted. If the lowest values are taken into account, as proposed, a close down of a majority of swimming pools in the EU seems to be a very likely outcome. We are of the opinion that this could clearly not be in the interest of the EU, the Commission, the Member States and its people. It seems to be irrational to artificially construe a conflict of interests (positive impacts of swimming vs. potential toxicological impacts). Operation of swimming pools requires adequate disinfection which should not impose any relevant risks to users. But the mere determination of data requirements to assess (potential) toxicological impacts must under no circumstance give cause for public or private swimming pool operators to decide on continuation or cessation of operations. Also, it must be taken into account that many values (such as trihalomethanes according to DIN 19643) are not employed with low limits because of mere toxicological reasons, but because the values are generally (with a lot of additional effort) achievable in practice although substantial investments are necessary. Bearing in mind that most public pools cannot be operated profitably, the general approach of choosing the lowest possible value would endanger the very existence of swimming pool operators and thus the Europe-wide ability of people learning how to swim.

The guidance document gives no indication what data, other than such already being under research (in part for decades, cf. Villanueva, Grummt, Zwiener etc.), is intended to be generated and which information is being expected.

C Availability of data and reliability of measurements

A quite significant number of research groups around the world research on the effects of disinfection by-products and have been doing so – in part – for decades, without being able to clearly measure the parameters, evaluate the toxicological and/or environmental effects and deduct reliable limit values. For many parameters this is still the case. We submit that it is at least questionable to expect a solution of these problems in connection with the approval of active substances according to the BPR.

D Utilization of existing standards with view to the monitoring of swimming pools

The German standard DIN 19643 is a Europe-wide recognized and utilized standard when dealing with swimming pool water treatment. In Germany, the monitoring of public swimming pools show that both users, operators and monitoring authorities have been able to manage and guarantee the public health using this standard, maximizing the use of filtration techniques and minimizing the use of biocides, thus minimizing the exposure to disinfection by-products. Keeping this in mind, it shall also be considered that the monitoring effort should be kept at reasonable levels. This leads us to the following proposals for solution:

E Solution proposals

- 1) Since there is no representative swimming pool, simplified testing of the established and measureable values in a specified swimming pool model seems to be appropriate and sufficient.
- 2) The specified swimming pool model should include three different pool types (swimmer pool, recreational/non-swimmer pool, paddling pool) with a water treatment and operation according to DIN 19643.

Note: a sophisticated model exists at the premises of TU Dresden and may be utilized for this kind of test.

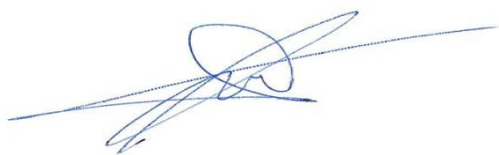
F Further remarks and course of action

Minimisation of water disinfectants, successfully practised in Germany and most countries of the EU for decades, through a combination of preparation and disinfection, means that ecological contamination has been all but eliminated. Moreover, in treating bathing-pool water, disinfectants used have little or no environmental impact. The minimal concentrations permitted in both drinking water/swimming-pool and bathing-pool applications have led to no known injury to people or the environment. After all, people today drink an average of two litres of water a day per capita and bathers enjoy hours on end in chlorinated water in a swimming bath without any anxiety. Through the use of water disinfectants, the hygiene requirements of Section 37 of the German Infectious Diseases Act are fully complied with. Bathing pool water treatment practice is monitored systematically by official bodies.

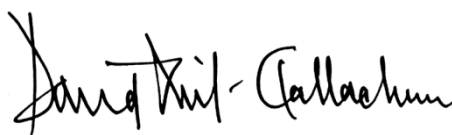
Taking this into account as well as the fact that measurement, evaluation and monitoring are difficult, we believe that it is reasonable to apply a simplified testing procedure on basis of a specified swimming pool model and to modify the guidance documents, respectively.

We offer our experts as support in executing this task.

SIGNATURES OF PRESIDENTS OR REPRESENTATIVES OF ASSOCIATIONS



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As to European Union of Swimming Pool and Spa Associations (“EUSA”)

The European Union of Swimming Pool and Spa Associations (EUSA) was founded in 2006 with its headquarters in Bruxelles. It represents craftsmen, the trade, wholesalers and the industry of the swimming pool and spa businesses in Europe.

Currently fourteen national swimming pool and spa associations are members of EUSA. The EUSA represents approx. 2,500 companies from all areas along the chain of adding value in the swimming pool and spa business.

As to Aqua Europa (“AE”)

AE, an International Association under Belgian law, is a confederation of European trade bodies representing the interests of the supply chain of the European water and wastewater industry. Membership is open to national industry associations active in the water sector which support the aims and objectives of AE in promoting the development of a fair and competitively healthy market place for all elements of the industry. We represent more than 100 manufacturers of water treatment devices and precursors.

AE is a registered stakeholder for the implementation of the BPR, in which context it is mainly focused on the impacts and requirements of the BPR on water and waste water treatment by in-situ-generated active substances. Our member companies are actively involved in the preparation of several dossiers for active substances approval, as well as biocidal product authorization according to the provisions of the BPR and especially CA-March15-Doc.5.1 and CA-May15-Doc.5.1.a.