Limitations of regulatory risk assessments of chemicals

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Abstract

The purpose of prospective risk assessment for chemicals is to identify potential risks prior to the use of substances. We challenged the environmental risk assessment, which is conducted under the European Biocidal Products Regulation 528/2012, and evaluated whether it covers all possible emissions of biocidal active substances from households into wastewater. Around 64 % of the observed applications of biocidal active substances do not fall its scope. Results show that gaps exist in the environmental risk assessment. An important approach to reduce possible risks by these substances in general would be to limit their use to in fact essential usages.

1. Introduction

The purpose of prospective risk assessments for chemicals is to identify potential risks for humans or environmental compartments like water bodies prior to the use of the substances. This is an important element to reach the Sustainable Development Goal (SDG) 6.3 to minimize the release of hazardous chemicals and SDG 12.4 to achieve the environmentally sound management of chemicals. Only with the knowledge which emissions of hazardous chemicals are relevant, these can be reduced in a goal-oriented manner.

Biocidal active substances (BAS) are substances designed to affect living organisms according to their definition in the *Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products* (BPR). Undesirable side effects on environment and health are thus likely to occur. In the EU, biocidal products (BP) are regulated under the BPR. Within this regulation, prospective risk assessment is carried out for the substances used as BAS. Applications for approval of BAS falling under BPR have to be submitted for each of the 22 different product types (PT), as described in Annex V of the BPR, in which the substance is intended to be used for a biocidal purpose. These include for example disinfectants, insecticides, repellents or preservatives. The European Chemicals Agency lists 295 BAS whose risks are currently assessed by the Member States ("under review") or are already approved in the EU. Approval has been sought for 796 active substance-PT combinations (European Chemicals Agency 2016). However, the aim of the authorisation procedure under BPR is only to find a 'safe use' for every single BP, where effects are below an unacceptable level, not to eliminate the effects as a whole.

Furthermore, BAS can simultaneously also be used in other product groups, which do not fall under the BPR, e.g. plant protection products (PPP), personal care products (PCP) or washing and cleaning agents (WCA). Article 2 of the BPR defines exemptions for these products falling under the scope of other regulatory instruments. The regulatory differentiation between BP and product groups falling under other regulations is complex (Woutersen et al. 2015). This can lead to borderline cases, for which it has to be decided on a case-to-case basis under which provision a product is regulated (European Commission 2015). This decision is based on the intended field of application of a product.

The consequence is that emissions of identical substances from applications, which are subject to different regulations, are not aggregated during the separate risk assessments. Households are likely to be major contributors to the total amount of BAS in sewage treatment plants. However, the specific sources within households are not yet fully understood (Bollmann et al., 2014a; Wittmer et al., 2011).Thus, possible wastewater emissions of BAS are maybe not completely evaluated and environmental risks could be underestimated. Information and data are, therefore, needed to close this knowledge gap regarding these possible emissions of BAS from households into wastewater and to what extent they are regulated under BPR. To account for possible gaps in risk assessment, measures for a sustainable use of BP are important.

Consumption data from households could be used to collect information on emissions of BAS from households, as it has been done for pharmaceuticals in the past (Herrmann et al. 2015; Le Corre et al. 2012). However, consumption data for BAS is not available in Europe. Besides a chemical characterisation of wastewater from households, the enquiry of consumption data by product inventories is a promising approach to examine emissions from households into wastewater. For a collection of data on the prevalence of BAS, different approaches can be used, e.g. telephone interviews, self-administered surveys or on-site visits (Hertz-Picciotto et al. 2010). Each of these methods has disadvantages and on-site visits are the most promising approach to collect detailed information. A highly sufficient approach to reduce the time required is the use of barcode scanners to inventory present products by the researcher (Bennett et al. 2012). Household investigations that included BAS, but were not focused on them, were conducted in Europe, e.g. in 30 households in one building in Copenhagen by on-site visits (Eriksson et al. 2003), in 2,281 households in France by telephone interviews and 23 households close to Angers and Nantes in France by on-site visits (ANSES 2010).

Within our study, we wanted to challenge the environmental risk assessment for biocides, which is conducted under the BPR, and evaluate whether it covers all possible emissions of biocidal active substances from households into wastewater. Thereby, we plan to identify possible limitations of the existing risk assessment concept and yet unidentified possible risks for wastewater treatment plants and receiving water bodies. The complete study already has been published in Wieck, Olsson & Kummerer (2016).

2. Methods

To get an overview over the used products and BAS, we established inventories of household products that could possibly contain BAS in 131 households in selected study sites in Northern Germany. These are representative of the three different urban-rural typologies in Europe: predominantly urban, intermediate and predominantly rural regions (BBSR 2009). Households were contacted, and in each household, one individual was asked whether he or she would be willing to participate in the study. Further information regarding the neighbourhoods and demographic characteristics can be found in Wieck, Olsson & Kummerer (2016).

The products that were used in the households were registered with the help of a barcode scanner. BAS can occur in various product groups in households. Besides other products for the control of pests (e.g. PPP) that may use the same active substances, BAS can also be found in PCP or WCA. In these products, they can be used as preservatives for the control of microorganisms or for other purposes. For this reason, to identify all possible sources of BAS in households, it is not enough to inventory only BP. In this study, the following product groups were inventoried:

- all products for the control of pests (incl. BP, PPP, products against fleas and lice on humans and pets) with a relevant release to wastewater;
- all WCA;
- certain PCP types with high release to wastewater: shampoo, body wash, bath additives, conditioner, soap, toothpaste, mouth wash, body lotion, hand cream, hair styling products, hair dye and make-up remover.

The ingredients of these products were evaluated, whether they contained BAS and whether the specific use of these substances is falling under the BPR.

3. Results and discussion

3.1 Regulation of BAS used in household products

BAS were present in all households, even though not all households possessed BP, as the majority of observations of BAS was in WCA and PCP, but not in BP. Around 64 % of the registered applications of BAS do not fall under the risk assessment of the BPR. The following uses, that are not covered, were identified (Figure 1):

1. In WCA, BAS which are not currently evaluated or approved for a use as a preservative (PT 6) were used 562 times. This represents 13.7% of the observations of BAS in all products.
2. In PCP, BAS were used 2,023 times (49.3%). In general, the use of BAS in PCP is not evaluated under the BPR, whether used as a preservative or not.
3. Additionally, BAS were found 33 times in pest control products other than BP (0.8%).

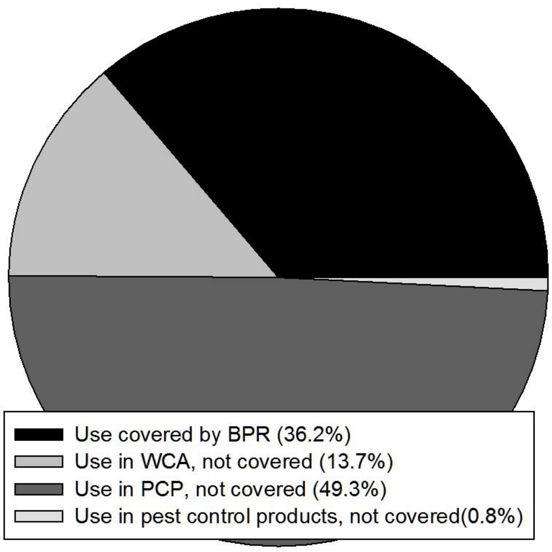

Figure 1 Risk assessment of biocidal active substances used in different product groups

Thus, it is an important contribution of this study to clearly highlight an important reason why risks for the environment are underestimated: because unregulated household emissions to municipal wastewater may occur. In total, 63.8% of the BAS uses observed here were not covered by the environmental risk assessment under the BPR. This percentage is based on 2,963 scanned products.

Some uses are in fact subject to environmental risk assessment under other legislation, such as substances in PPP under *Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC* (European Union 2009), or substances in PCP, whose environmental risk assessment is delegated to *Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals* (REACH, European Union 2007). However, REACH is not designed for environmental risk assessment of substances with intended effects on target organisms; this is why, in principle, all active substances are subject to risk assessments under their own regulations (like the BPR). But this is not true for biologically active preservatives in PCP, an omission which has already been criticised by Tarazona (2014). Example risk assessments for preservatives in PCP show possible risks for sewage treatment plants (Carbajo et al. 2015) and preservatives have been identified as “down-the-drain” chemicals used in households, which may be of concern (Rotsidou & Scrimshaw 2015).

But even if the regulations for each substance were to include detailed environmental risk assessment regarding all its respective uses, the aggregate environmental exposure due to its different uses falling under different regulatory areas would still be neglected. An aggregated exposure assessment would be necessary to conduct realistic chemical risk assessments, but this is not current practice (Dudzina et al. 2015). This is one example of the limitations of the risk assessment of chemicals: Although the complexity of these assessments is already high, there are still black spots that are missed by existing methods (Backhaus, Brooks & Kapustka 2010).

A sustainable use of BP would reduce the use of the products to the minimum necessary and thus reduce the emissions to the environment. To achieve a sustainable approach that strengthens the use of inherently safe chemicals and the development of alternative chemicals and procedures, ideas have been gathered (UBA 2014). The developed concept includes a set of different measures that go beyond the current prospective risk assessment practices. Depending on the environmental concerns to be addressed and the specific use conditions of the presumed problematic biocidal products, appropriate measures can be chosen from this set. It includes measures such as the development of best practice codes or the introduction of mandatory training and further education for professional users. Furthermore, requirements for sales (e.g. prohibition of self-service and internet sales for products with certain substances) or the development of standards for equipment for the application of biocides could lead to a more sustainable use.

3.2 Plausibility

In order to assess whether the method of product scanning was successful to inventory all products containing BAS in households with emission to wastewater, the results are compared with recent monitoring results of BAS in municipal wastewater and STP effluent throughout Europe (Table 1).

Table 1: Measured concentrations of BAS in wastewater and STP influent and effluent (amended after Wieck, Olsson & Kummerer 2016)

Substance	Matrix	Measured maximum concentration	Reference	Found in products?
Bayrepel-acid (metabolite of icaridin)	STP effluent	0.1 - 1 µg L^{-1}	Reemtsma et al. (2006)	Yes
Benzalkonium chloride (C12-18)	STP influent	170,000 ng L^{-1}	Clara et al. (2007)	Yes
Carbendazim	STP influent STP influent STP influent	143 ng L^{-1} 78 ng L^{-1} < 670 ng L^{-1}	Wick, Fink & Ternes (2010) Bollmann et al. (2014) Kupper et al. (2006)	No
Cybutryne	STP influent STP influent	21 ng L^{-1} 8 ng L^{-1}	Wick, Fink & Ternes (2010) Bollmann et al. (2014)	No
DCOIT	STP influent	Detected, but not quantified	Bollmann et al. (2014)	No
DDAC (C10-18)	STP influent	200,000 ng L^{-1}	Clara et al. (2007)	Yes
DEET	STP effluent	0.1 - 1 µg L^{-1}	Reemtsma et al. (2006)	Yes
Diuron	STP influent STP influent	39 ng L^{-1} 68 ng L^{-1}	Bollmann et al. (2014) Wick, Fink & Ternes (2010)	No
Isoproturon	STP influent STP influent	39 ng L^{-1} 43 ng L^{-1}	Wick, Fink & Ternes (2010) Bollmann et al. (2014)	No
Methylisothiazolinone	STP influent	Detected, but not quantified	Bollmann et al. (2014)	Yes
Octylisothiazolinone	STP influent STP influent	11 ng L^{-1} Detected, but not quantified	Wick, Fink & Ternes (2010) Bollmann et al. (2014)	Yes
Permethrin	STP influent	< 670 ng L^{-1}	Kupper et al. (2006)	Yes
Piperonyl butoxide	Wastewater	172 ng L^{-1}	Rodil et al. (2009)	Yes
Propiconazole	STP influent STP influent	16 ng L^{-1} 4,540 ng L^{-1}	Wick, Fink & Ternes (2010) Bollmann et al. (2014)	No
Salicylic acid	STP influent	89,133 ng L^{-1}	Kosma, Lambropoulou & Albanis (2014)	Yes
Tebuconazole	STP influent STP influent	78 ng L^{-1} 8.9 ng L^{-1}	Bollmann et al. (2014) Wick, Fink & Ternes (2010)	No
Terbutryn	STP influent STP influent	116 ng L^{-1} 62 ng L^{-1}	Wick, Fink & Ternes (2010) Bollmann et al. (2014)	No
Triclosan	STP influent STP influent	1,742 ng L^{-1} 841 ng L^{-1}	Kosma, Lambropoulou & Albanis (2014) Wick, Fink & Ternes (2010)	Yes

This comparison shows that, while some BAS that are found in wastewater were also detected in the scanned products, other BAS found in wastewater were not scanned in the households. These substances, like diuron, isoproturon or carbendazim, are often components of outdoor paints and might enter combined sewer systems via stormwater. As outdoor paints are not usually stocked in households, products containing these substances may not have been comprehensively inventoried in our survey. Product inventory can be an important tool to identify specific sources, but should be complemented by chemical analyses.

For other substances, the monitoring results support the scanning results and indicate a measurable contribution from the household products to wastewater. However, some of the substances were detected only in a few products, which alone are not enough to explain positive monitoring results. For example, in the case of triclosan, the results show that this BAS was only found four times, as an ingredient in toothpaste (n=131). Considering the findings of several studies which have detected triclosan in wastewater, the data obtained here cannot account for the concentrations measured in these studies. Possible explanations are that not all products containing triclosan were inventoried (e.g. deodorant or treated articles) or that the monitoring results from earlier studies no longer reflect current use. Chemical analyses of the wastewater of one of the neighbourhood are therefore scheduled in the future to allow for direct comparison to the survey results there.

For a high number of substances, no monitoring results for their presence in wastewater are available. This does not necessarily mean that they are not present, but could simply imply that not all relevant substances in wastewater have been monitored yet. This could be the result of a process that Daughton (2014) calls the "Matthew Effect". Chemicals that have already been frequently detected in the environment tend to become the focus for scientists more than the so-called "Matthew Effect Orphaned Chemicals," which have been less often observed. As the regulation of BAS is relatively new – the *Directive 98/8/EC concerning the placing of biocidal products on the market* only entered into force in 1998 (European Union 1998) – there is still much ignorance concerning their occurrence in the environment. Thus, our results contribute urgently needed information regarding their potential occurrence in wastewater. Accordingly, these new findings can be used to adjust corresponding BAS monitoring programs to allow for target-oriented and thus cost-efficient monitoring programs.

4. Conclusion

The results show that gaps exist in the environmental risk assessment of biocidal active substances. Considering the number of observations of BAS in the scanned products, PCP and WCA clearly outnumber BP as emission sources of active substances in wastewater. Consequently, risks are underestimated because not all of these emission sources are considered during environmental risk assessment under BPR. If risks are identified under this environmental risk assessment, risk mitigation measures only tackling the use of BP will not be sufficient for all BAS, because emissions to wastewater might still occur from other product categories.

The attempt to solve the problem would require an extensive increase of complexity of risk assessments and their aggregation throughout all legislation. From our point of view, a better approach to reduce possible risks by these substances in general would be to limit their use to in fact essential usages. A sustainable use of biocides should thus be promoted to account for the limitations in the environmental risk assessment of these substances. This could be a promising approach to reach the SDGs of minimizing the release of hazardous chemicals.

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