BACKGROUND // APRIL 2018

Recommendations for reducing micropollutants in waters

German Environment Agency

Umwelt Bundesamt

Imprint

Publisher:
German Environment Agency
Section II 2.1 General Aspects of Water and Soil
PO Box 14 06
D-06813 Dessau-Roßlau
Tel: +49 340-2103-0
info@umweltbundesamt.de
Internet: www.umweltbundesamt.de

/umweltbundesamt.de
/umweltbundesamt
/umweltbundesamt
/umweltbundesamt

Authors:
M. Ahting, F. Brauer, A. Duffek, I. Ebert,
A. Eckhardt, E. Hassold, M. Helmecke, I. Kirst,
B. Krause, P. Lepom, S. Leuthold, C. Mathan,
V. Mohaupt, J. F. Moltmann, A. Müller, I. Nöh,
C. Pickl, U. Pirntke, K. Pohl, J. Rechenberg, M. Suhr,
C. Thierbach, L. Tietjen, P. Von der Ohe, C. Winde

Edited by:
Helmecke, M. (II 2.1)

Design:
Atelier Hauer + Dörfler GmbH

Publications as a pdf:
www.umweltbundesamt.de/publikationen

Photo credits:
shutterstock.com
Design of Figures 2–9 rendered by Studio GOOD

As at December 2017

ISSN 2363-829X

BACKGROUND // APRIL 2018

Recommendations for reducing micropollutants in waters

Contents

List of abbreviations

AbwAG
Abwasserabgabengesetz (Wastewater Charge Act)

AbwV
Abwasserverordnung (Wastewater Ordinance)

AwSV
Ordinance on Installations for Handling Substances Hazardous to Water

BLAC
Bund/Länder-Arbeitsgemeinschaft Chemikaliensicherheit (Working Group of the Federal States on Chemical Safety)

BMBF
Bundesministerium für Bildung und Forschung (Federal Ministry of Education and Research)

BMEL
Bundesministerium für Ernährung und Landwirtschaft (Federal Ministry of Food and Agriculture)

BMU
Bundesministerium für Umwelt, Naturschutz und nukleare Sicherheit (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety)

BAT
Best Available Techniques

CLP Regulation
Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures

COHIBA
Control of Hazardous Substances in the Baltic Sea Region

EAC
Environmental Assessment Criteria

ED
Endocrine Disruptor

EMA
European Medicines Agency

PE
Population Equivalent (treatment plants)

FKZ
Forschungskennzahl (project code number)

GK
Größenklasse (size category, treatment plants)

HPV
Health-based Parametric Values

HMP
Human Medicinal Product

HELCOM
Baltic Marine Environment Protection Commission, or Helsinki Commission

LAWA
Working Group of the Federal States on Water Issues (Bund/ Länder-Arbeitsgemeinschaft Wasser)

IED
EU Industrial Emissions Directive 2010/75/EU

MSFD
Marine Strategy Framework Directive

NAP
National Action Plan for the sustainable use of plant protection products

nrM
Non-Relevant Metabolites

PAH
Polycyclic Aromatic Hydrocarbons

PBT
Persistent, Bioaccumulative and Toxic substances

PFC
Per- and Polyfluorinated compounds

PEC
Predicted Environmental Exposure

PFOA
Perfluorooctanoic Acid

PFOS
Perfluorooctanesulfonic Acid

PMT
Persistent, Mobile and Toxic substances

PNEC
Predicted No Effect Concentration

PPP
Plant Protection Product

OGewV
Oberflächengewässerverordnung (Surface Water Ordinance)

OgRe
Relevance of organic trace elements in rainwater runoff in Berlin

OSPAR
Convention for the Protection of the Marine Environment of the North-East Atlantic (Oslo-Paris-Convention)

RAC
Regulatory Acceptable Concentration

REACH
Registration, Evaluation, Authorisation and Restriction of Chemicals

RiSKWa
Risk Management of Emerging Compounds and Pathogens in the Water Cycle

SOA
State of the Art

SVHC
Substances of Very High Concern

VMP
Veterinary Medicinal Product

UBA
Umweltbundesamt (German Environment Agency)

EQS
Environmental Quality Standard

VO
Verordnung (Ordinance)

vPvB
Very Persistent and Very Bioaccumulative

WGK
Wassergefährdungsklasse (Water Hazard Class)

WHG
Wasserhaushaltsgesetz (Federal Water Act)

WRMG
Wasch- und Reinigungsmittelgesetz (German Detergent and Cleaning Products Act)

WFD
EU Water Framework Directive 2000/60/EC

1. Introduction

For more than a decade, and thanks largely to refined analytical methods, substances in the concentration ranges of micrograms down to nanograms per litre (µg–ng/l) have been increasingly detected in water courses, in groundwater and in drinking water. These so-called micropollutants are traces of medicinal products, plant protection products, biocides and other chemicals that can already have detrimental effects on the environment or human health at very low concentrations.

Numerous research projects (e. g. COHIBA [1], RiSKWa [2], OgRe [3], Strategie Mikropoll Schweiz [4]) in recent years have addressed the "substance pollutions of waters" and the necessity to take reduction measures. The German Environment Agency (Umweltbundesamt, UBA) has commissioned a number of research projects [5] and international bodies (such as the Rhine Protection Commission [6]) have reached decisions and developed strategies on this subject matter. The German federal states (Länder), in particular North Rhine Westphalia [7] and Baden-Württemberg [8], are working on suitable solutions, have established competence centres and have already equipped 19 sewage treatment plants with a fourth (quaternary) treatment stage. In Switzerland, the legal bases for introducing additional measures into wastewater treatment (4th treatment stage) came into force at the beginning of 2016 [9].

An essential legal obligation to reduce and prevent micropollutants arises from the European Water Framework Directive (WFD) and the environmental quality standards (EQS) for priority substances defined in the daughter directive of the WFD. Within Germany, these and other river-basin-specific pollutants are nationally regulated in the Surface Water Ordinance (Oberflächengewässerverordnung, OGewV).

To aim exclusively at meeting individual environmental quality standards that already exist for priority substances, however, would address only a fraction of the problem. The UBA is therefore pursuing a holistic, precautionary approach. In addition to protecting the aquatic ecosystems and their biodiversity and ensuring that drinking water can be obtained using natural treatment methods, this approach also helps protect against an enrichment of pollutants in sediments and oceans. The abovementioned legal provisions must therefore be continually verified and revised according to the state of knowledge. It is also necessary to search systematically for other substances that have detrimental effects on the environment, and to evaluate those substances.

Reducing micropollutants requires a cost-effective combination of reduction measures at the source, during the use of substances as well as end-of-pipe measures.

With this paper, the German Environment Agency shows what measures for reducing the entry of micropollutants are already provided for in the scope of the existing regulations, what approaches can improve the reduction of pollution, and where there is still need for research or action.

The selection of reduction measures presented in this paper takes into consideration the relevance of the source, the possibilities of their implementation, the timeframe within which the measure will become effective (time horizon) and – wherever estimable – the costs.

This position paper complements the UBA position paper of March 2015 "Organic micropollutants in waters – fourth treatment stage for less pollution" ("Organische Mikroverunreinigungen in Gewässern – Vierte Reinigungsstufe für weniger Einträge" [10]), in which we presented key aspects of advanced wastewater treatment.

The measures presented below pick up on the recommendations of the Stakeholder Dialogue on the Federal Government's Strategy for Trace Substances ("Spurenstoffstrategie des Bundes" [11]) and develop them further.

2. Definition of micropollutants

We define micropollutants as those substances that are generally present in water bodies in low concentrations (typically in the range of ng–µg/l) but which can have detrimental effects on humans, the environment or drinking water supplies in these concentrations. This includes transformation and degradation products (metabolites) of the original substances.

This paper focuses on organic micropollutants of anthropogenic origin, and specifically on the substance groups of medicinal products, plant protection products, biocides, chemicals (under REACH), washing detergents and cleaning agents. Inorganic chemicals, microplastics and nutrients are not dealt with in this paper, given that they can have greatly varying characteristics and behaviours, or that other reduction measures may apply (e. g. Minamata Convention on Mercury [12], UBA studies on microplastics [13]). No comparable reduction measures can be developed for substances of geogenic origin.

3. Objective

Anthropogenically produced substances brought into circulation are undesirable in water bodies, even in the smallest concentrations. In the Federal Water Act (WHG), the management objectives for water bodies clearly reflect this in articles §§ 27, 44 and 47 of WHG, as do the pollution control specifications in articles §§ 32, 45 and 48 of WHG. These demand the avoidance of any deterioration of the chemical status of waters, and regard detrimental changes to the water composition as impermissible. Article § 57 of WHG also accounts for the principle of prevention and reduction, in that it only allows discharge of wastewater into water bodies if the amount and harmfulness of the wastewater can be kept as low as possible by applying the best available technology. The greater the demonstrated impact on the protected properties “man” and “environment”, the greater the necessity to keep these substances away from all water bodies. Pollution of drinking water must be prevented and reduced for the sake of purity regulations and as a general precaution. Prevention and reduction measures must account for the substance properties and satisfy the regulations presented below.

Harmful substance properties

Especially relevant to the water cycle are substances with properties that are toxic to humans or the environment, as well as substances that are persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) or endocrine-active. Also to be regarded as very critical are substances that are persistent or pseudo-persistent [14], mobile and toxic in the water cycle (PMT). Substances with these properties have the potential, among other things, to pollute the raw water used for producing drinking water. These are difficult to remove by technical means during drinking water treatment or considerably increase the effort and expense of treatment.

The ecotoxicological significance of certain medicinal products, such as pain killers, antibiotics, antidepressants and beta-blockers, has been determined in various laboratory and field studies [15]. Above all active substances with hormonal or hormone-like effects can already have detrimental effects on aquatic life when present in very low concentrations, including effects such as feminization of male fish and snails.

Depending on the substance properties, effects can also be delayed and can appear in places far from the source of contamination. Even substances that are present for a short time or only locally in water bodies, and are therefore often difficult to detect, can present a high risk to aquatic organisms due their toxicity, which is highly acute in some cases, or can lead to problems in any further water use. Furthermore, the processes of degradation of certain substances can yield transformation products and metabolites that have very different environmental behaviour and sometimes much higher toxic potential than that of the original substance. Radiocontrast agents, for example, are commonly regarded as toxicologically harmless even though it is known that some radiocontrast agents can break down into transformation products of high toxic potential (e. g. products of iopamidol due to chlorination). This is above all relevant considering the detection of radiocontrast agents in drinking water.

Necessity of a combined and precautionary approach (and legal framework)

Given the substance properties described above, there is a need for a precautionary approach in handling micropollutants to adequately protect ecology and health. Comprehensive water protection (including surface waters, oceans and groundwater) should be achieved by a combination of precautionary measures at the source and during product use, the implementation of the best available technologies for reducing downstream emissions, and adherence to and continual development of environmental quality objectives (e. g. environmental quality standards).

A particular notion of the precautionary principle is presented in article § 62 of the Federal Water Act (WHG), which imposes requirements for installations that handle substances hazardous to waters. As a subordinate legislation to this paragraph, the Ordinance on Installations for Handling Substances Hazardous to Water (AwSV) contributes a concept for preventing pollution in waters already at the source. The AwSV regulates the classification of substances and mixtures into Water Hazard Classes (*Wassergefährdungsklassen*, WGK), based on the intrinsic properties of the substances and mixtures. The WGKs are indexes by which the graded technical safety requirements for installations are defined. The more dangerous the substance, the stricter the requirements. Substances that are not classified into any Water Hazard Class are treated as substances of the highest Hazard Class WGK 3. This legal fiction implements the precautionary principle anchored in article § 62 WHG in exemplary fashion.

The EU Water Framework Directive (WFD) and Marine Strategy Framework Directive (MSFD) create a legally binding regulation framework for achieving (and maintaining) good ecological and/or chemical status. Aside from provisions for achieving the objectives, the WFD and the MSFD also prohibit deterioration. The daughter directive of the WFD, Directive 2008/105/EC (on environmental quality standards, amended by Directive 2013/39/EU) lays down environmental quality standards for 45 priority and priority hazardous substances of EU-wide relevance. These substances are evaluated for the chemical status of surface waters. The priority hazardous substances are substances to be phased out, which should no longer be detectable in the environment within one generation. Thirteen of the 45 substances are persistent organic pollutants (POPs), whose manufacture and use are already banned or heavily restricted by Regulation (EC) No. 805/2004.

Germany implements this nationally with its Surface Water Ordinance (OGewV 2016), which, in addition to the abovementioned 45 substances (Annex 8) regulates 67 so-called river-basin-specific pollutants (Annex 6). The latter are used for evaluating the ecological condition of surface waters.

For marine protection, it was agreed in the Convention for the Protection of the Marine Environment of the North-East Atlantic (Oslo/Paris or OSPAR Convention) and the Baltic Marine Environment Protection Commission (Helsinki Commission or HELCOM), to end the discharge, emission and spillage of "hazardous substances" into the marine environment by the year 2020. This applies to PBT, vPvB substances and substances that give rise to an equivalent level of concern. The intention is to achieve this goal by implementing relevant European laws, international conventions and recommendations at the level of the respective marine convention.

Further relevant specifications are laid down in regulations specific to substance groups.

Table 1

Legal bases for handling micropollutants

EU Regulations	
Water Framework Directive (WFD) 2000/60/EC	Objective to achieve/maintain good chemical and ecological status of waters; prohibition of deterioration; measures for reducing relevant pollutants/pollutant groups (Annex VIII of the WFD); demand to phase out priority hazardous substances
Groundwater Directive (GWD) 2006/118/EC	Specifications for good groundwater chemical status; reversal of significant and sustained upward trends in concentrations of pollutants; environmental quality standards (EQS) for pesticides and parameters for threshold values Measures for achieving/maintaining good water status and for preventing or limiting the input of pollutants
Directive 2008/105/EC on Environmental Quality Standards, amended by 2013/39/EU	Environmental quality standards (EQS) for so-called priority and priority hazardous substances (Annex X of the WFD), defining "good chemical status" with respect to surface waters. Presently, EQSs are defined for 45 substances; 12 of which are only included in the assessment of chemical status since 2018. The list is revised every 6 years. A "watch list" is being created to facilitate the future prioritisation process.
Marine Strategy Framework Directive (MSFD) 2008/56/EU	Objective to achieve/maintain good status of the marine environment; prohibition of deterioration; measures for reducing relevant pollutants/pollutant groups
REACH Regulation (EC) 1907/2006 (Registration, Evaluation, Authorisation & Restriction of Chemicals)	Registration, evaluation, authorisation and restriction of chemicals; official evaluation of dossiers and substances ensures sufficient information is known about the substances. Official instruments for risk management exist in the form of identification of substances of very high concern (SVHC) (from an environmental perspective these would be PBT, vPvB substances and endocrine disruptors (ED)), possible authorisation requirements and restrictions.
CLP Regulation (EC) 1272/2008 (Classification, Labelling & Packaging)	Classification and labelling inventory (approximately 114,000 substances classified as hazardous)
Plant Protection Product Regulation (EC) No. 1107/2009	Authorisation, placing on the market, use and control of plant protection products. List of active substances approved in the EU.
Directive 2009/128/EC on the sustainable use of pesticides	Commitment to a sustainable, permanent environmentally friendly use of pesticides; creation of National Action Plans for the Member States
Regulation (EU) 528/2012 on biocidal products	Authorisation of biocidal products based on an environmental risk assessment of active biocidal substances and biocidal products. List of active substances approved in the EU.
Directive 2001/83/EC (amended by 2004/27/EC) on the Community code relating to medicinal products for human use	The authorisation of human medicinal products requires testing for potential impacts on the environment. If a risk to the environment is identified, denial of authorisation is not possible; authorisation can be subjected to conditions for the protection of the environment.
Directive 2001/82/EC (amended by 2004/28/EC and 2009/9/EC) on the Community code relating to veterinary medicinal products	The authorisation of veterinary medicines requires testing for all possible impacts on the environment. If a risk to the environment is identified, authorisation can be denied or be subjected to conditions for the protection of the environment.

EU Regulations	
Regulation (EC) No. 726/2004 on Community authorisation procedures and establishing a European Medicines Agency	Additional legal requirements for the authorisation of new human and veterinary medicinal products
Regulation (EC) No. 648/2004 on detergents	Regulates complete aerobic biodegradation of surfactants and derogations for placing surfactants on the market
Directive 2010/75/EU on industrial emissions	Sets out the requirements for the construction, operation and cessation of operations of industrial installations. Industrial operations may require an EU-wide permit and must be operated according to the best available techniques
National Regulations	
Federal Water Act (Wasserhaushaltsgesetz, WHG)	Federal objectives for managing waters (§§ 27, 44 and 47 WHG) and pollution control specifications (§§ 32, 45 and 48 WHG): Specifications for achieving objectives and avoiding any deterioration of the chemical status of waters and detrimental changes to the water composition. Allows discharge of wastewater into water bodies only if the amount and harmfulness of the wastewater can be kept as low as possible by applying the best available techniques (§ 57 WHG); Permission can also be denied if the management objectives cannot be achieved with the best available techniques (§ 12 WHG). Lays down safety requirements for facilities that handle substances hazardous to water (§ 62 in conjunction with the Ordinance on Facilities for Handling Substances Hazardous to Water (AwSV))
Surface Water Ordinance (Oberflächengewässerverordnung, OGewV)	Implementation of the EQS Regulation in national law; specification of river-basin-specific pollutants
Groundwater Ordinance (Grundwasserverordnung, GrwV)	Implementation of the GWD in German law; specification of groundwater threshold values (including plant protection products and active biocidal substances)
Plant Protection Act (Pflanzenschutzgesetz, PflSchG)	Authorisation and use of plant protection products
Chemicals Act (Chemikaliengesetz, ChemG) – Section IIA (implementing Regulation (EU) 528/2012)	Authorisation procedure for biocidal products. Testing and evaluating all impacts on human health and the environment
Medicinal Products Act (Arzneimittelgesetz, AMG) of 1976, last amended 10 Dec. 2015	Authorisation and trade with medicinal products for human beings and animals
Detergents and Cleaning Products Act (Wasch- und Reinigungsmittelgesetz, WRMG)	Regulates the manufacture, labelling and sale of washing detergents and cleaning products in Germany; also regulates the primary biodegradability of surfactants and cosmetic products

Source: German Environment Agency

4. Presence of micropollutants in waters

The presence of micropollutants in German surface waters, in the groundwater and in the Baltic Sea has been proven in various studies [16]. There are many assessment criteria available for evaluation the substance concentrations, ranging from legally binding quality standards to guideline values in non-binding memoranda.

Environmental quality standards according to Directive 2013/39/EU and OGewV

Environmental quality standards describe a quality objective for surface waters, as derived from ecotoxicological and human-toxicological data according to the EU Technical Guidance for Deriving Environmental Quality Standards – No. 27 (TGD-EQS). The EQSs are legally binding, being stipulated in the daughter directive of the Water Framework Directive (on environmental quality standards, 2008/105/EC amended by 2013/39/EU) and nationally implemented in Germany in the Surface Water Ordinance (*Oberflächengewässerverordnung*, OGewV). Targets of protection for maintaining "good chemical status" or "good ecological status" are the aquatic ecosystems, including protection of predators against secondary poisoning; human health when consuming fish from inland surface, coastal and ocean waters; and raw water obtained from surface waters for producing drinking water.

EQS exceedances of river-basin-specific pollutants in surface waters can be detected for certain pesticides (plant protection products and biocides) at the measuring points set by the Working Group of the Federal States on Water Issues (*Bund/Länder-Arbeitsgemeinschaft Wasser*, LAWA). EU-wide environmental quality standards have been exceeded by pesticides, PAHs and a number of persistent organic pollutants (POPs) [17]. Metals are excluded in these observations.

Table 2

Exceeded EQSs measured in Germany

Exceeding of the EU-wide EQSs for priority and other pollutants	Exceeding of EQSs for river-basin-specific pollutants
PESTICIDES*	PESTICIDES*
Diuron	Bentazon
TBT	Mecoprop
Bifenox	Chloridazon
Cybutryn	2,4 D
Dichlorvos	Flufenacet
Isoproturon	Imidacloprid
	Nicosulfuron
INDUSTRIAL CHEMICALS	Triclosan
Polycyclic aromatic hydrocarbons (PAH)	Diflufenican
	Picolinafen
	Triphenyltin cation
SUBSTANCES IN THE STOCKHOLM CONVENTION (POPs)	SUBSTANCES IN THE STOCKHOLM CONVENTION (POPs)
BDE	PCBs
HCB	
Heptachlor	
PFOS	

* Pesticides: plant protection products and biocides

Source: Compiled by the German Environment Agency according to data from the Working Group of the Federal States on Water Issues (LAWA), 2016

Proposed environmental quality standards

Human medicinal products have so far not been defined as priority substances EU-wide, nor as river-basin-specific substances in the German Surface Waters Ordinance. For some human medicinal products, however, proposals for appropriate environmental quality standards have already been drafted at the European and German national level (see Table 3).

Comparing the proposed environmental quality standards with the average annual readings at the LAWA measuring points for 2013–2015 reveals that the analgesics/anti-inflammatory drugs diclofenac and ibuprofen very often exceed the limits. Isolated exceedances have been detected for the anti-epileptic carbamazepine, the antibiotic clarithromycin, the natural hormone 17-β-estradiol and its synthetic derivate 17-α-ethinylestradiol [22].

Concentrations of the antibiotic sulfamethoxazole close to the proposed EQS have been detected at the outlets of urban wastewater treatment plants. Accordingly, exceedances of the proposed EQS are possible in the case of low-flow conditions and high wastewater percentages in water bodies (LAWA 2016).

If no EQSs or proposed EQSs exist for given substances, then alternative references for evaluating maximum permissible concentrations are Predicted No-Effect Concentrations (PNECs) and Regulatory Acceptable Concentrations (RACs).

Groundwater threshold values according to the Groundwater Ordinance

For the protection objective "good chemical status of the groundwater", EU-wide environmental quality standards apply to nitrates and to active substances in plant protection products and biocidal products, including related metabolites. These are complemented by nationally defined threshold values pursuant to the Groundwater Directive. These thresholds are implemented in the Groundwater Ordinance (*Grundwasserverordnung*, GrwV).

GrwV lays down a threshold for pesticides (plant protection products and biocides) of 0.1 µg/l. According to the most recent figures for Germany in the period of 2009 to 2012, this threshold is exceeded at 4.6 % of all groundwater measuring points investigated (approximately 13,000 measuring points) [23].

No corresponding threshold values have been defined yet for medicinal products. Upon investigation of 15 German states in 2013, 16 medicinal products were detected in the groundwater at concentrations in excess of 0.1 µg/l [24].

Table 3

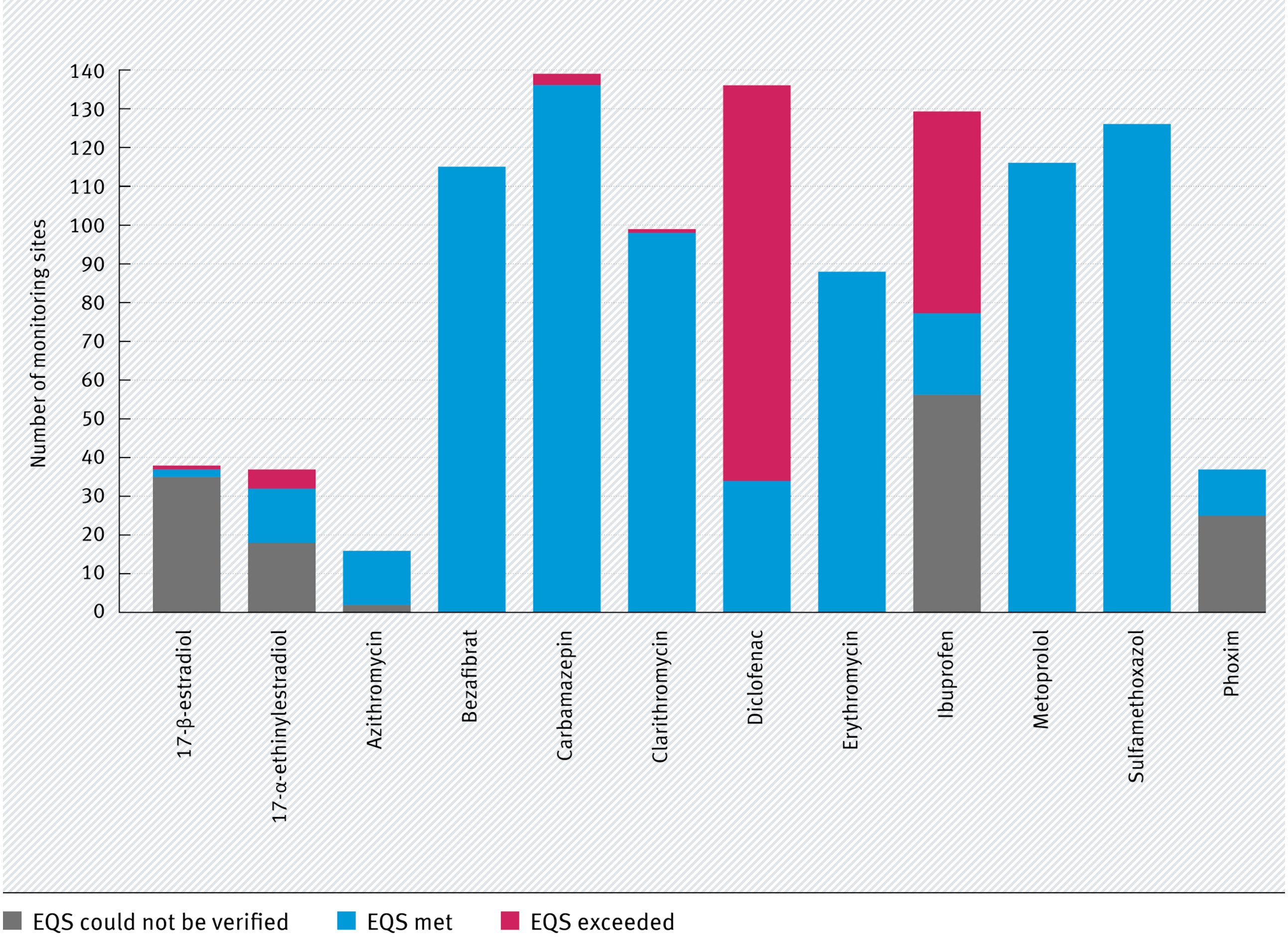
Environmental quality standards proposed for the annual average of medicinal products

Name of substance	EQS [µg/l]	Source
17-α ethinylestradiol	0.000035	Carvalho, R.N.et al. (2016) [18]
17-ß estradiol	0.0004	Carvalho, R.N.et al. (2016)
Azithromycin	0.09	Carvalho, R.N.et al. (2015) [19]
Bezafibrate	2.3	Wenzel, A. et al. (2015) [20]
Carbamazepine	0.5	Wenzel, A. et al. (2015)
Clarithromycin	0.13	Carvalho, R.N.et al. (2015)
Diclofenac	0.05	Carvalho, R.N.et al. (2016)
Erythromycin	0.2	Carvalho, R.N.et al. (2015)
Ibuprofen	0.01	Summary Dossier (2015) [21]
Metoprolol	43	Wenzel, A. et al. (2015)
Sulfamethoxazole	0.6	Wenzel, A. et al. (2015)

Source: German Environment Agency

Figure 1

Comparison of 2013–2015 annual averages with proposed EQSs for medicinal products (LAWA monitoring points)



Source: Federal Environment Agency based on data supplied by Working Group of the Federal States on Water Issues (LAWA), 2016

No extensive investigations or threshold values exist for industrial chemicals in groundwater.

Guiding values of European water suppliers

The European drinking water suppliers have developed guiding values in a memorandum with the aim of raising the quality of water in those surface water bodies from which drinking water is obtained to a level where drinking water can be produced using only near-natural treatment methods [25].

The target value of 0.1 µg/l is widely exceeded in streams by various active pharmaceutical ingredients (e. g. metformin, gabapentin, diclofenac and carbamazepine) and radiocontrast agents (e. g. iopamidol and iomeprol), including their metabolites (e. g. valsartan acid and DHH-carbamazepine) and transformation products (e. g. carboxy-acyclovir). Exceedances of the guiding values for benzotriazole, phosphoric acid esters and aromas have also been detected with high frequency [26].

From the group of plant protection agents and biocides, concentrations above 0.1 µg/l were measured at 40–60 % of the German measuring points when investigating selected indicator substances such as glyphosate, its metabolite AMPA, and the metabolites of the active substances metazachlor, metolachlor-metazachlor sulfonic acid and metolachlor sulfonic acid. These results are especially relevant to areas where bank filtrate is used for obtaining drinking water [27]. For substances without drinking water guiding values or threshold values as defined by the Drinking Water Ordinance, health-based parametric values (HPV) [28] provide an evaluation basis for "drinking water" as an object of protection.

Watch list

In order to aid future prioritisation processes (according to Article 16 paragraph 2 WFD), the EU is creating a watch list of substances for which observation data are being collected throughout the European Union. It lists those substances that were recognised as having a potential to exceed the proposed environmental quality standards, but for which there was not enough Europe-wide monitoring data – or only data with a limit of detection below the proposed environmental quality standards – to warrant the inclusion of these substances in the list of priority substances. The watch list [29] includes several active pharmaceutical ingredients (diclofenac, 17-α-ethinylestradiol (EE2), 17-β-estradiol (E2), estrone (E1), and the macrolides erythromycin, clarithromycin and azithromycin).

The EU Commission will update the watch list every 2 years.

A German watch list has been created by LAWA for updating the list of river-basin-specific substances (OGewV 2016, Annex 6).

For groundwater, there is furthermore another watch list being established at the European level for monitoring selected potentially problematic substances that could be included in the next amendment to the Groundwater Directive.

Lack of basis for comparison

Reliable toxicological and ecotoxicological comparative values, from which it can be unequivocally determined whether a substance is harmful for man and water bodies, do not exist for all substances, let alone for their transformation/degradation products.

Even for some substances for which an environmental risk assessment has been performed, there is still lack of knowledge and uncertainty as to their short-term and long-term effects and interactions in mixtures. Although existing EQSs do account for safety factors, mixtures of substances and their potentially additive effects or interactions cannot be adequately reflected. Accordingly, in addition to chemical analysis, the possibility of using biological effect tests is currently being investigated for determining the effects of mixtures of substances.

The current derivation of EQSs according to the EU Technical Guidance Document [30] does not take into account the pathway of groundwater infiltration or the use of surface waters for obtaining drinking water. These entry pathways, however, are especially relevant in the case of mobile and persistent substances such as radiocontrast agents.

It would be desirable to introduce further environmental quality standards, among other things for active pharmaceutical ingredients, since this would allow targeted monitoring and reduction measures to be initiated. EQSs have been suggested for certain active substances, while some substances have been included in the WFD watch list (see above). There are still no river-basin-specific or EU-wide environmental quality standards defined, or threshold values derived, for medicinal products in groundwater.

In order to improve the monitoring of substance groups, it is recommendable to specify indicator substances that can be used as references for drawing conclusions about the general pressure levels of micropollutants for bank filtrate and ground water, for example. Furthermore, this can be helpful to better understand natural processes and the need for action with respect to controlling technical treatment methods.

5. Entry pathways

The sources of micropollutants in waters are greatly varied and depend primarily on how the substance are used or, in the case of transformation products/metabolites, where they are produced (figure 2). Frequently driven by rainfall, micropollutants is introduced into waters from point sources or from diffuse sources (large areas).

One significant point-source entry pathway is sewage disposal. In Germany, sewage is disposed of through separate or combined sewer systems. Separate sewer systems carry sewage and rainwater through separate pipelines while combined sewers carry them together through the same pipelines.

Medicinal products (excreted or improperly disposed of), laundry and dishwasher detergents, biocides and common household chemicals are transported into communal treatment plants with sewage. Adding to this are emissions from many industrial operations (e.g. car repair shops) and public establishments (e.g. hospitals).

Substances used outdoors (for example biocides and chemicals from roofing fabric, facade paint, tyre wear, plant protection products in gardens/allotments, public greenery or sports fields) are transported into the sewer network (combined sewer system) or directly into water bodies (separate sewer system) with rainwater. Substances that are not degraded or retained in vegetated ground can make their way into the groundwater by seepage through unsealed surfaces.

In heavy rain events, combined sewer systems, which account for about 40 % of the existing German sewer networks, can become overloaded and result in so-called combined sewer overflow. When this happens, the combined water overflow carries a mixture of untreated sewage and rainwater, containing for example residues of biocides, chemicals and plant protection products, into waters.

Sewage containing pollutants from manufacture or processing (depending on the industry) are treated in industrial treatment plants (direct dischargers).

After treatment of sewage in a communal or industrial treatment plant, the resulting water is typically drained into water bodies. Because some pollutants cannot be fully eliminated in the treatment plant, these necessarily also get into the water bodies.

Substances that are used outdoors, above all plant protection products, biocides or chemicals, can get directly into surface water by surface runoff, drainage or drift. Groundwater can be polluted through seepage or bank filtration.

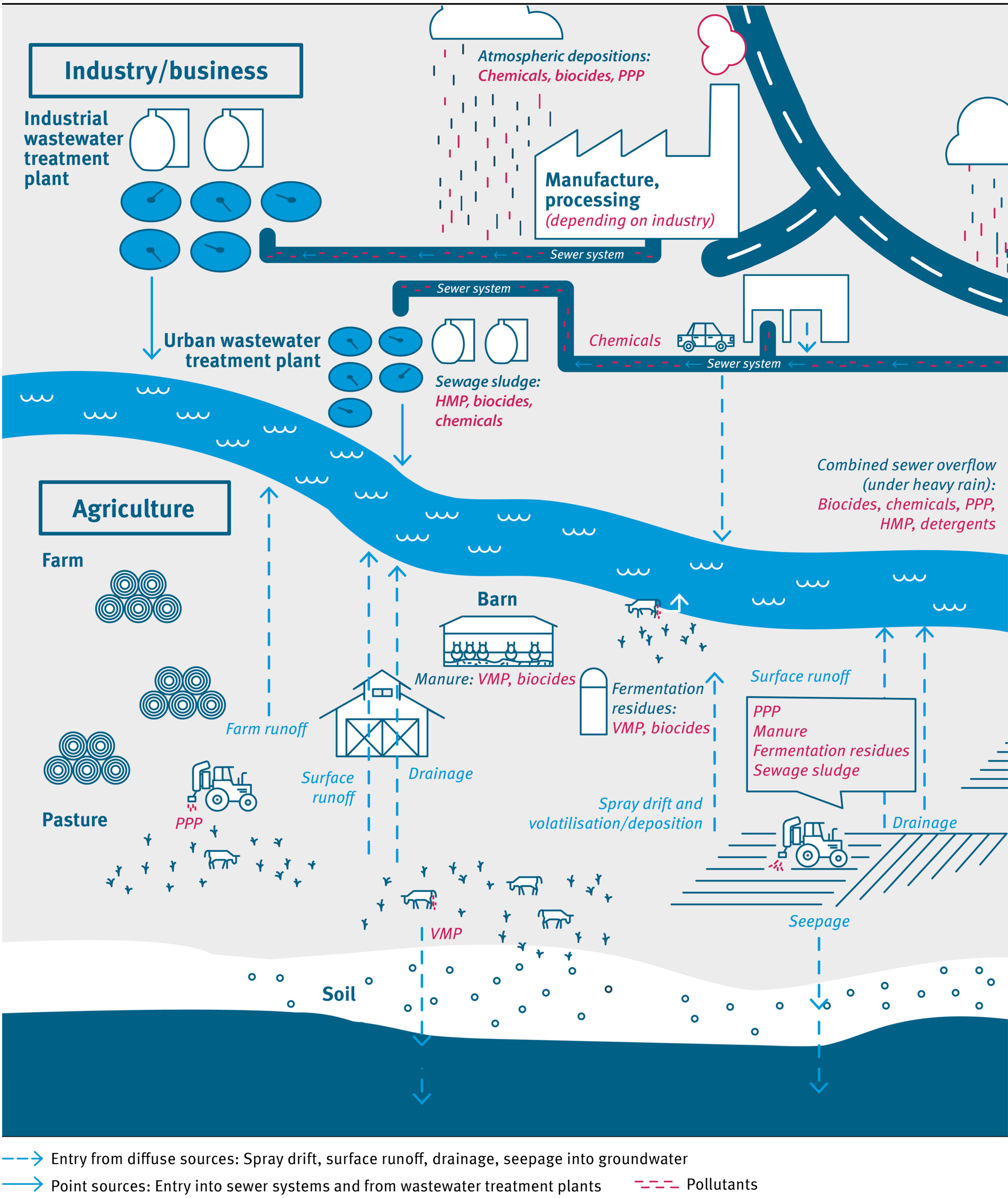
Other potential entry pathways for micropollutants are deposition from the air (e.g. polycyclic aromatic hydrocarbons (PAH) or plant protection products), accidents in the use or transport of substances that are hazardous to water, improper handling during the manufacture, processing, transport or use of substances and products, remobilisation of substances from sediment following flood events or construction work, the emission of chemicals (e.g. paints) and biocides from hydraulics installations and ships (e.g. antifouling paints) and improper disposal. Substances are also introduced from aquaculture processes (for example animal feed, medicinal products, transformation products or metabolic products).

To quantify the entry pathways, one needs material flow analyses. Hillenbrand et al. (2014)[31] have created these for selected substances using the modelling tool MoRE[32].

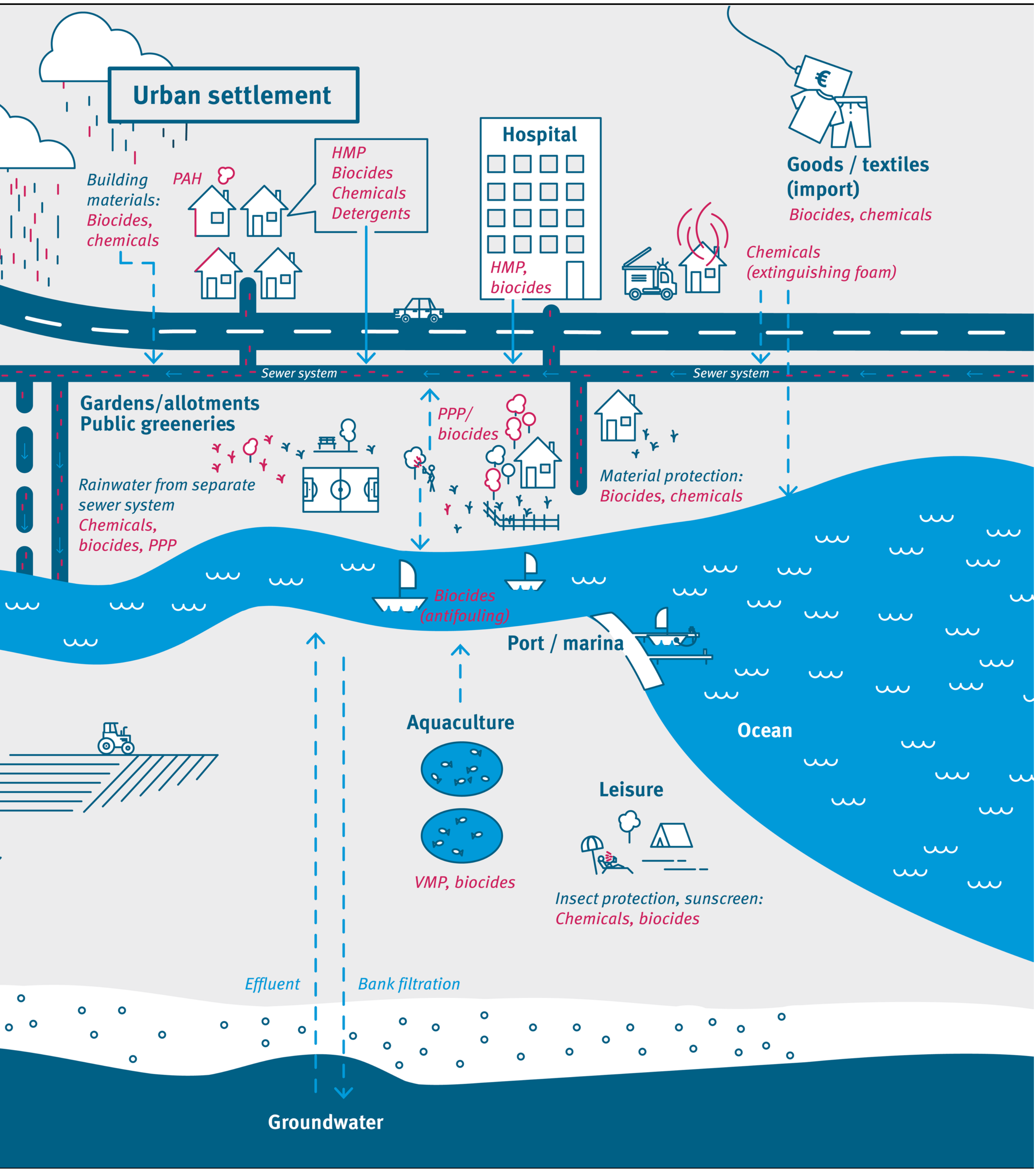
It is clear that micropollutants from many sources, falling under various regulatory scopes, can get into the environment, in particular into waters. Substances usually exist in environmental compartments together with other substances, which can interact with each other as "environmental mixtures" that subsequently present higher toxicities/risks.

Figure 2

Schematic overview of possible entry pathways of micropollutants into waters



HMP Human medicinal products; VMP Veterinary medicinal products; PPP Plant protection products; PAH Polycyclic aromatic hydrocarbons



Source: German Environment Agency

6. Measures to reduce specific substance groups

6.1 Criteria for evaluating potential measures

In order to assess the effectiveness and efficiency of the many measures that could be potentially employed at the source, in use and end-of-pipe, a set of criteria is needed. For this assessment and prioritisation of measures, we apply the following criteria:

- *Effectiveness* in terms of the measure's potential to reduce emissions: substance flow analyses and substance emission models can provide insights into this [33]. The assessments made in the present document are based on expert opinions, taking the significance of each entry pathway into consideration. On this basis, we classify measures into categories of low (-), moderate (o) or high (+) expected effectiveness.

- *Specificity*: does a measure address only one single substance, i. e. is it substance-specific, or will it address a wide range of substances?

- *Effectiveness horizon*: when can the first positive effects, i. e. reduced pollution, be expected? We distinguish between short-term < 5 years, medium-term < 10 years, and long-term > 10 years.

- *Costs (cost-effectiveness)*: what are the costs for the expected effectiveness? Factors to include are, wherever calculable, investment, operating and transaction costs. A positive (+) assessment is given for low costs (or high cost-effectiveness), while a negative (-) assessment is given for high costs (or low-cost-effectiveness).

- *Feasibility*: this refers as much to the technical feasibility – e. g. the degree of maturity, reliability or adaptability of the measure to the various given conditions, or in other words the ability to implement the (technical) approach – as to the corresponding target group's acceptance of implementing the planned measure. We distinguish between immediately feasible measures (+), not yet immediately feasible measures (o), and measures that still clearly need action in terms of technological development, acceptance or funding (-).

6.2 Human medicinal products

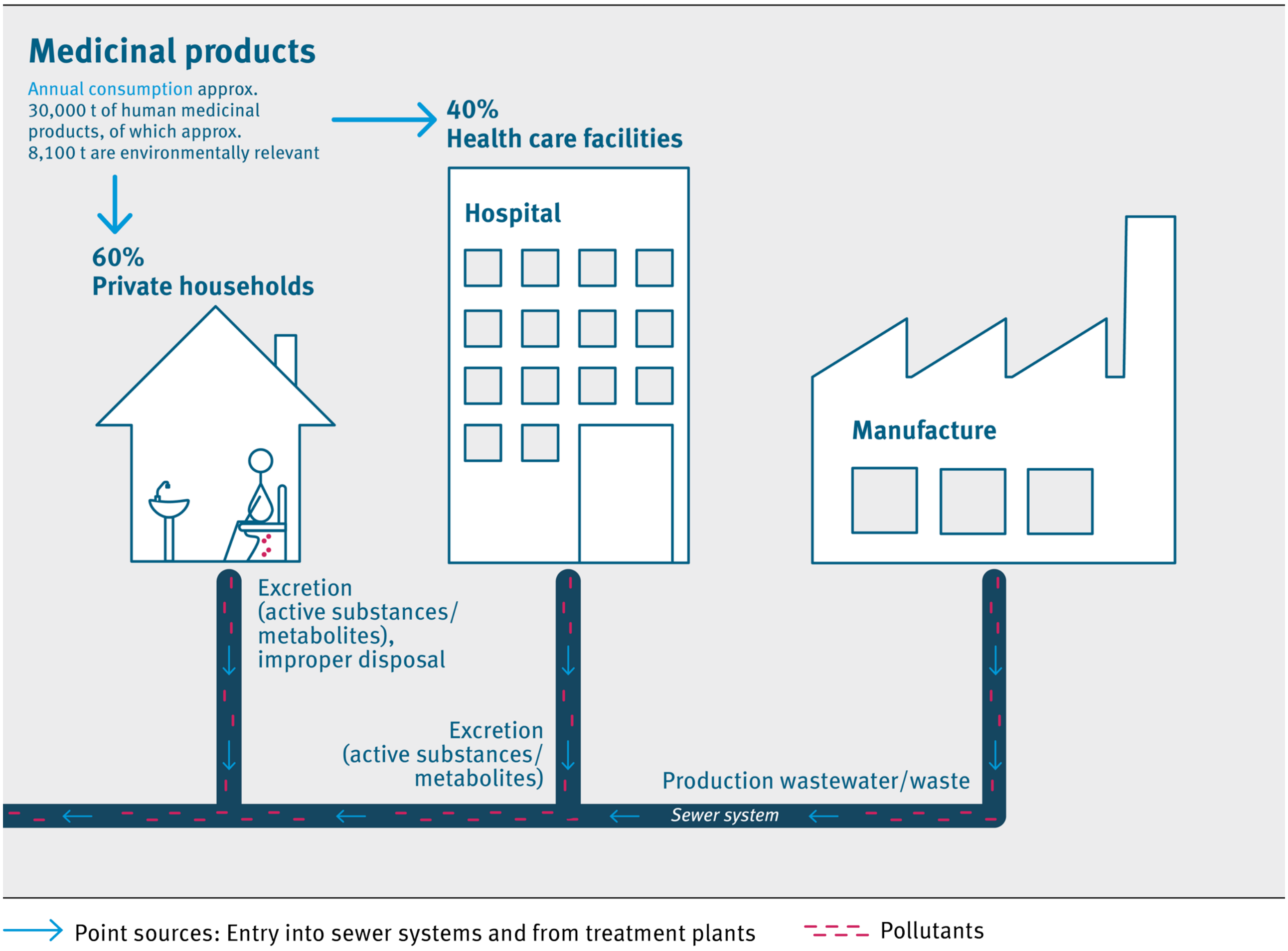
The annual consumption of human medicinal products in Germany is estimated at 30,000 t, at a total of 2,300 active substances (reference year 2012). Around 1,100 of these active substances are not considered environmentally relevant per se because they are counted among the electrolytes, peptides, vitamins etc. and are excluded from environmental assessment. Accordingly, in Germany, there are currently 1,200 potentially environmentally relevant active substances from human medicinal products, at an annual consumption of around 8,100 t [34].

Active substances from human medicinal products are emitted from hospitals, health care facilities and private households along with human excretions into the municipal sewer system (Figure 3). When used as directed, unmodified active substances are excreted along with the metabolites formed from them in the body into the wastewater. Smaller amounts are also introduced into the sewer system from manufacturing processes and from improper disposal down sinks and toilets. Depending on the design of a treatment plant and the nature of an active substance, the substance can make its way into surface waters. Active substances can therefore get into the drinking water through bank filtration or from surface waters. According to estimates by pharmaceutical companies [35], the main sources of human medicinal products in surface waters are patient excretions (88 %), improper disposal down sinks or toilets (10 %) and manufacturing processes (2 %). Regarding improper disposal, other sources claim that up to 47 % of consumers always or occasionally dispose of unused medicinal products improperly [36].

In the authorisation process for human medicinal products, risk assessments are typically based on an estimate of exposure and effect put forth in the guideline of the European Medicines Agency EMA [37]. Even if a risk to the environment is identified, it cannot be used as grounds for denying authorisation because environmental risks are not a component of the final risk-benefit assessment. The only current option for protecting the environment is to stipulate conditions of use, labelling and disposal. The EMA guideline addresses the properties of an active substance, for example PBT (persistent, bioaccumulative and toxic) or

Figure 3

Schematic illustration of possible entry pathways of human medicinal products into wastewater



Source: German Environment Agency. Data: IMS Health (2013)

ED (endocrine disruptive), using specifically developed test systems to detect these effects. However, an environmental risk or hazard posed by these properties does not automatically result in non-authorisation.

The greatest potential for reducing the environmental risk of human medicinal products lies in implementing measures to minimise their entry via wastewater. The authorisation process for medicinal products, by contrast, only offers very limited possibilities. Environmental risk assessments deliver valuable information about substances, which could be used to derive EQSs, for example, provided the information is made publicly available. In most cases, however, the environmental data are still treated confidentially – a situation that needs to be redressed (see below). Consequently, specific reduction measures also have to be developed and implemented outside the medicinal product authorisation process. Generally, achieving a given reduction target requires a combination of measures at different levels. Various initiatives and projects have therefore been initiated, among others by the UBA, with the aim of not only taking direct reduction measures, but also of increasing communication and education on a more environmentally friendly handling of medicinal products, and measuring the environmental impact of medicinal products [38].

6.1.1 Creating and improving evaluation bases and criteria

The following measures are necessary for environmental concerns to be included more strongly in future in the process of medicinal product authorisation:

- **Introducing a monograph/master file system for active pharmaceutical ingredients**
  This means departing from the existing practice of evaluating a formulated product, in favour of evaluating the active substances and keeping these evaluations in so-called “active substance

monographs/master files". The collective data in this system should be applied at the European level for "new" active substances as well as for "old" active substances that have not (yet) been environmentally assessed, and promises more consistent, up-to-date assessments as well as resource savings, greater animal protection and better availability of environmental data from each substance evaluation. At present, in most cases, the environmental data from substance evaluations are not publicly available. Publication in a central database would help to increase transparency and make it easier for other stakeholders such as water providers, water disposers and the water authorities of the Länder to manage problematic substances.

- **Considering widening the requirement for a prescription in the human medicinal products sector**
  Compulsory prescription is an effective way to control the use of medicinal products at a national level in the interests of health. It is known that the percentage of non-prescription medicines, especially analgesics, is steadily increasing in the total consumption of medicinal products in Germany, and has already reached an order of magnitude similar to that of prescription medicines [39]. It is therefore worth investigating whether the prescription requirement can be widened to account for the environmental risk aspects of highly problematic medicinal products (for example those of high relevance to drinking water). Further research and discussion are still needed to assess the legal enforceability and risk reduction potential of this measure.

6.1.2 Measures at the source

- **Developing and harmonising effective reduction measures within the authorisation process**
  Risk reduction measures for environmental protection can be made mandatory by law within the medicinal product authorisation process; in other words, if a risk is identified in an environmental assessment, then practicable reduction measures would have to be formulated and implemented. Currently, however, there are only very few appropriate and effective obligations to minimise the risk of human medicinal products. This demands further research.
  The inclusion of environmental risks in the final risk-benefit assessment of the human medicinal product authorisation process also needs to be discussed further, so that more options for action can be introduced into legislation, such as post-authorisation measures in the interest of environmental pharmacovigilance.

Outside the authorisation process, the following measures are worthwhile:

- **Boosting research into environmentally friendlier active pharmaceutical ingredients and dosage forms – "green pharmacy"**
  Currently there are only isolated projects, e. g. by the German Federal Environmental Foundation (*Deutsche Bundesstiftung Umwelt*), promoting the trend towards "green" pharmaceuticals or dosage forms, which are easier to filter out in treatment plants, for example, and will therefore not enter the waters. The same goes for finding alternatives to those active substances that persist in the environment and can cause long-term problems with the drinking water. Clearly far more incentive and funding needs to be created for the pharmaceutical industry and research institutions to show more commitment. One option could be to set a special research priority of "green pharmacy", for example, at the Federal Ministry of Education and Research (*Bundesministerium für Bildung und Forschung, BMBF*). There is also discussion about promoting environmentally friendly alternatives by granting longer patent protection.

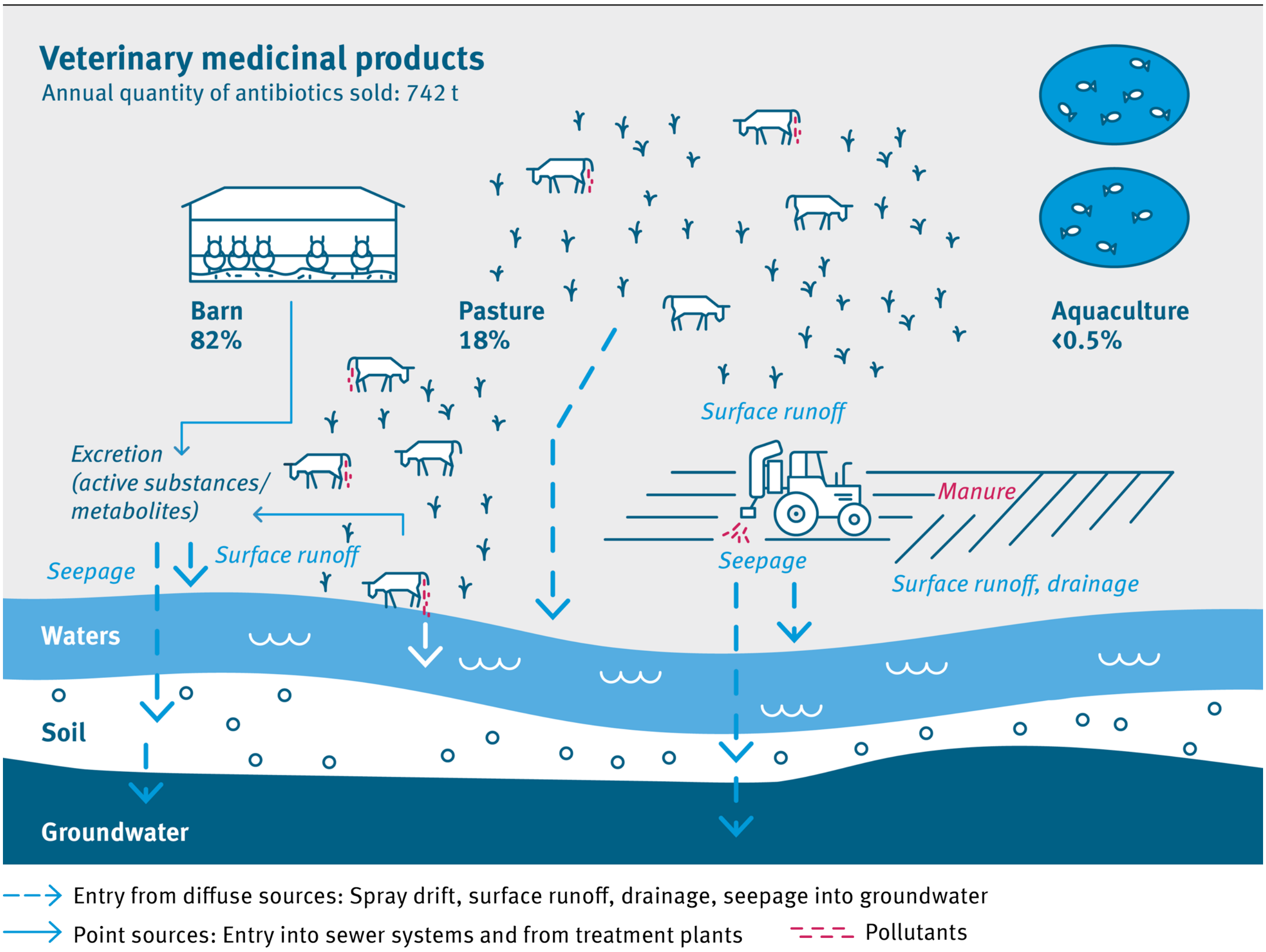
6.1.3 Measures in use

The most important post-authorisation risk-reduction possibilities are:

- **Educating and informing specific target groups on the environmentally friendly use of medicinal products**
  Wherever possible, the use of medicinal products should be complemented and supplemented by other measures for maintaining health, such as exercise and healthy nutrition. Physicians, pharmacists, health insurance companies, and even patients and consumers must be informed of how the use of medicinal products can be optimised in the interests of the environment. A discussion process regarding this extensive topic needs to be struck up with all members of society. The UBA

Figure 4

Schematic illustration of possible entry pathways of veterinary medicinal products into waters



Source: German Environment Agency. Data: BVL (2017), EMA (2015), Destatis (2011)

published conceptual considerations and recommendations for targeted education and information in 2017 [40]. The factors behind the increasing use of pharmaceuticals should also be analysed in this context. This measure can be implemented nationally in the medium to long term.

- **Education about proper disposal: "No pharmaceuticals down the toilet or sink!"**
  According to estimates, 10 % of pollution in the form of medicinal product residues is created by improper disposal down sinks or toilets. Education about the proper disposal is therefore a necessary, yet relatively low cost and effective reduction measure. Nationwide campaigns should be held, including the involvement of the pharmaceutical industry, to provide comprehensive information addressed to specific target groups [41]. It would appear beneficial to include a specific notice of proper disposal on the outer packaging of pharmaceuticals, in addition to the standard disposal notice on the package insert, however, this is currently rejected at the European level. A common explanation for this rejection is the fear that such a notice could have a negative effect on the medicine intake.

6.3 Veterinary medicinal products

There are around 430 active substances authorised in Germany as veterinary medicinal products, some 270 of which can be classified as environmentally relevant in that they do not count among the substances excluded from environmental assessment, such as electrolytes, peptides, vitamins etc. Some of the authorised veterinary medicinal products are also authorised as human medicinal products, therefore the source cannot always be clearly discerned when found in waters. The amount of antibiotics dispensed to veterinarians in 2016 was 742 t [42]. No reliable data exists for the other active substance groups.

Depending on the nature of the soil, veterinary medicinal products from manure and fermentation residues applied to agricultural land can seep into the groundwater or enter the surface waters via run-off during heavy rainfall events.

Veterinary medicinal products are largely used in agriculture to treat animals such as cattle, pigs, chickens, turkeys, sheep, goats and horses. The large share of the active substances are excreted from the animals in unmodified form.

The main entry pathway of veterinary medicinal products is from farm manure on agricultural land (Figure 4) [43]. From there, the residues of the active substances of veterinary medicinal products and their metabolites formed in the animals' bodies and present in the animal excrements can make their way directly or via runoff into adjacent surface waters. If they are not retained by the soil components, they can get into the groundwater and, very rarely, even into the raw water from which we obtain our drinking water. With regard to food-providing animals in Germany, the relevance of pollution sources in terms of the amount contributed by each form of livestock farming is, in descending order: **Indoor systems** (82 % – cattle, pigs, poultry) > **Pasture-raised** (18 % – cattle, sheep, goats, horses) > **Aquaculture** (< 0.5 %) [44].

The environmental risk assessment of veterinary medicinal products for livestock also follows harmonised guidelines [45]. Denial of authorisation of veterinary medicinal products is possible since environmental aspects are included in their risk-benefit assessment. In this case, the benefits are weighed up against the risks. Usually, veterinary medicinal products are authorised even if environmental risks have been identified because the benefit is believed to outweigh the risk to the environment or because no alternative active substances exist. Generally, the environmental risk assessments performed in the authorisation process for veterinary medicinal products are the same as for human medicinal products. Veterinary medicines with specific effects, e. g. endocrine effects, are tested according to a tailored risk assessment. In 2016, a guideline was passed at the European level for the hazard-based assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products [46].

While many reduction measures, such as communication and education, apply equally to human and veterinary medicinal products, some measures are aimed specifically at reducing environmental pollution by veterinary medicinal products. In the case of veterinary medicinal products, the greatest reduction potential lies in applying regulatory and technical measures to limit the entry of residues into the environment from farm manure. Overall consumption of veterinary medicinal products can also be reduced by optimising various framework conditions in, for example, preventive health management or in animal raising, feeding and hygiene [47].

6.3.1 Creating and improving evaluation bases and criteria

- **Introducing a monograph/master file system for active pharmaceutical ingredients**
  See the measures for human medicinal products.

6.3.2 Measures at the source

- **Developing and harmonising effective reduction measures within the authorisation process**
  Risk reduction measures for the protection of the environment can also be made mandatory for authorisation. Certain Europe-wide harmonised risk reduction measures for animal medicinal products (e. g. temporarily limiting treated pasture animals' access to waterbodies) are summarised in a "Reflection Paper" from the EMA [48]. However, there is still need for further individual measures.

  Measures for the veterinarian profession and agriculture to reduce veterinary medicinal product pollution encompass several areas of activity: minimising the use of veterinary medicinal products, preventive measures for improving animal health, measures in the storage, preparation and application of manure, and good agricultural practice. In a research project, UBA has identified more than 40 measures we recommend to be implemented [49].

- **Banning veterinary medicinal products with PBT/vPvB properties**
  Veterinary medicinal products containing active substances with PBT or vPvB properties should not make their way into the environment, and should generally not be authorised or even removed from the market in Germany or EU-wide, given that there are no effective risk reduction

measures for these problematic substances. A proposed provision to this effect is currently being discussed for the European Regulation on Veterinarian Medicinal Products. UBA already presented its opinion on the most important demands for the Veterinarian Medicinal Products Regulation in its 2015 position paper [50].

- **Researching on changing the right to dispense**
  Veterinarians are currently entitled to produce, mix, store and sell pharmacy-only and prescription medicines (as their right to dispense). It should be investigated whether, and to what extent, a change to the right to dispense presents a possibility to limit the use of veterinary medicinal products at the national level. This still requires further discussion.

- **Boosting research into environmentally friendlier active pharmaceutical ingredients and dosage forms – "green pharmacy"**
  See the measures for human medicinal products.

6.3.3 Measures in use

- **Educating and informing specific target groups on the environmentally friendly use of medicinal products**
  Those working in agriculture and veterinary medicine should receive specific education and further information on the topic of veterinary medicinal products and the environment. For the purpose of awareness-raising, at the end of 2017, UBA presented material for the education and further training of veterinarians and apprentices in the field of agriculture, and also created brochures and an internet portal [51]. Environmental aspects should also be given greater consideration in future in umbrella initiatives such as the German Antibiotic Resistance Strategy (*Deutsche Antibiotika-Resistenzstrategie*, DART) [52].

The new EU Veterinary Medicinal Products Regulation is currently in development. Germany has already contributed various points for strengthening environmental concerns, such as taking environmental aspects into consideration in the reclassification of veterinary medicinal products especially from terrestrial animals to aquaculture, banning PBT/vPvB substances, and improving the environmental assessment and data availability by introducing a monograph/master file system. These measures will also help at the national level to minimise the entry of problematic substances into the environment.

An integrative pharmaceuticals strategy is also currently being developed at the EU level. This is fundamentally the correct level of regulation for certain measures since the prerequisites for authorising the marketing of human and veterinarian medicinal products are defined here. By 2018, the European Commission wants to present a strategy with concrete measures that concern both legislative and non-legislative spheres. We recommend the measures presented in Table 4 be addressed in this context.

Table 4

Assessment matrix of selected measures for medicinal products for human and veterinary use

Measures	ffectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
Developing and harmonising risk-reduction measures within the authorisation process	-/o	Spec.	o/+	2	+
Banning PBT substances in veterinary medicinal products	+	Spec.	n.d.	2	-
Researching environmentally friendlier active ingredients / dosage forms	-	Spec.	-	3	o
Target-group specific communication and information	o	Br.	+	2–3	+
Running information campaigns on the proper disposal of unused pharmaceuticals	+	Br.	+	2–3	+
Monograph system for active pharmaceutical ingredients	+	Spec.	o	3	+
Considering widening the requirement for a prescription taking into account environmental concerns	n.d.	Spec.	o	n.d.	o
Research on how modifying the right to dispense may potentially affect the use of veterinary medicinal products	n.d.	Spec.	o	n.d.	o

Expected effectiveness: (+ high), (0 moderate), (- low), (n.d. no data, uncertain), (spec.: measure is substance-specific), (br.: measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term ‹ 5 years), (2 = medium term ‹ 10 years), (3 = long term › 10 years)
Costs: (+ low), (0 moderate), (- high), (n.d. no data, uncertain)
Feasibility: (+ immediately feasible), (o not yet immediately feasible), (- still clear deficits/need for action (need for research, funding or acceptance))

Source: German Environment Agency (expert assessment)

The assessment in Table 4 shows that the selected measures are expected to become effective only in the medium to long term. With the exception of information/communication measures, the other measures are substance-specific. For substance-specific measures, the expected entry reductions and costs depend on the substances and therefore no blanket cost estimates can be made. As with regard to the suggested research projects on possible reduction approaches, any statements on the effectiveness, costs and time horizon of their implementation can only be concretised once the respective research results are in.

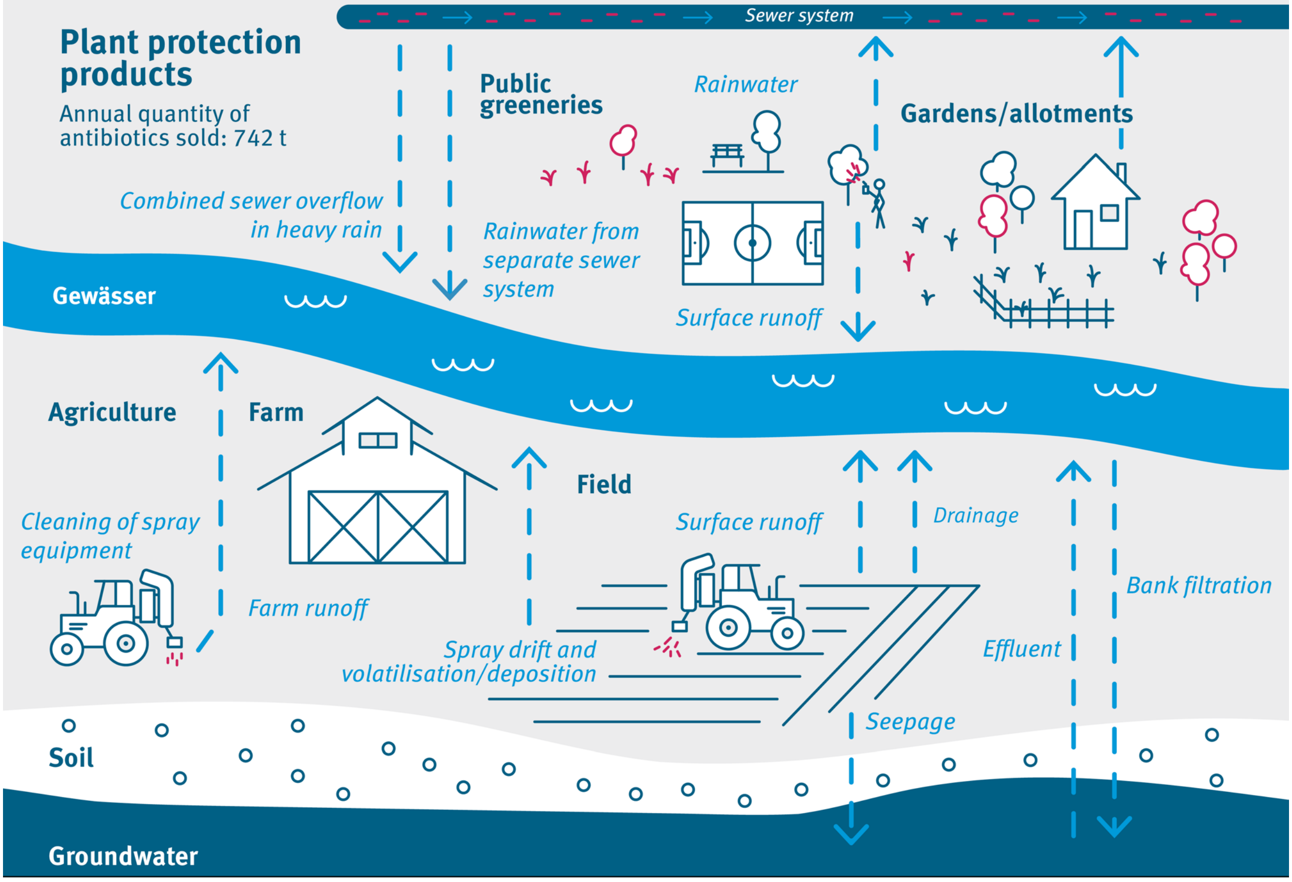
Limitations for immediate implementation are anticipated, among other things, in the form of resistance (e.g. to the ban on medicinal products with PBT properties) and lack of incentive for funding (especially for research).

6.4 Plant protection products

The residues of plant protection products (PPP) and their metabolites can be found in many waters. Monitoring programmes by the Federal states (Länder), water utilities and research projects repeatedly reveal exceedances of quality objectives [53, 54, 55]. Small water bodies in the agricultural landscape, in particular, are exposed to PPP pollution, given that they are used openly in the environment over large areas and in considerable quantities. The domestic sales in 2015 amounted to 34,238 t of active substances for professional use and 514 t for non-professional use such as in gardens, allotments and in public greenery [56]. Based on political commitment to sustainable, or in other words permanently environmentally friendly, plant protection though the EU Sustainable Use Directive (2009/128/EC), the German government has announced further measures in its National Action Plan (NAP [57]) for preventing or minimising the entry of PPPs into groundwaters and surface waters.

Figure 5

Schematic illustration of possible entry pathways of plant protection products into waters



Entry from diffuse sources: Spray drift, surface runoff, drainage, seepage into groundwater

Point sources: Entry into sewer systems and from treatment plants

Pollutants

Source: German Environment Agency Data: BVL (2016)

The German Environment Agency believes the environmental and nature protection objectives stated in the NAP are, however, too unambitious to bring about a substantial improvement. Furthermore, the measures associated with the objectives are not binding or specific enough, and are only poorly implemented in some areas. In its 5-point programme [58], the German Environment Agency presents the basic principles for sustainable plant protection, and these principles simultaneously serve as a guideline for the measures suggested below.

Given their open use in the environment, plant protection products make their way into the waters via many different pathways (Figure 5). The essential pathways include diffuse entry in the form of spray and dust drift during application, surface runoff, direct seepage, drainage systems, bank filtration and volatilisation with subsequent deposition, and point sources such as farm runoff due to improper cleaning of spray equipment.

In order to prevent unacceptable effects of PPPs, a strict testing and approval procedure according to the European Regulation (EC) No. 1107/2009 exists in conjunction with the German Plant Protection Act (*Pflanzenschutzgesetz*, PflSchG). However, this unwanted entry and the effects of PPPs in waters cannot be entirely prevented. Reasons for this include, among others, potential evaluation gaps in the procedures, not fully estimable residual risks, considering individual applications only in isolation (authorisation for indicated use only) rather than the total load of PPPs, or improper use of PPPs or non-compliance with specified risk reduction measures such as distance requirements.

Working from the basic principles of the 5-point programme for sustainable, environmentally friendly plant protection, we have selected measures for water protection that

- significantly reduce the dependency on chemical-synthetic plant protection and thus reduce the total load of PPPs on the environment,
- better identify and communicate the risks and effects on human health and the environment,
- address the identified risks with improved standards and risk management, and
- make it verifiable whether the protection of waters strived for in the authorisation process is in fact reached in reality.

6.4.1 Creating and improving evaluation bases and criteria

- **Combining prospective risk assessment and monitoring data in the authorisation process**
  If one is to verify whether the protection level for waters striven for in the environmental risk assessment is in fact reached in reality, monitoring data that allow a comparison with the prospective risk assessment (including risk management measures) in the PPP authorisation process are indispensable. Determining the pollution status involves both chemical monitoring (monitoring the temporal and spatial occurrence of substance concentrations) and biological monitoring, so that it is also possible to detect effects that have only been poorly estimated in the risk assessment so far (e.g. indirect effects, effects of the consequences of spraying and combination effects). This could lead to adaptations in the risk assessment of PPPs.

  As of 2018, the National Action Plan (NAP) provides for Germany-wide representative random sampling of the pollution of small water bodies in the agricultural landscape. A concept for event-based **small waters monitoring** is currently being agreed upon. This will also address those recommendations of the German Advisory Council on the Environment (*Sachverständigenrat für Umweltfragen* SRU) [59], which asserts that substance monitoring of surface waters should be more event-based than has been the case so far, and that sample should be taken in particular when and where pollutant entries are expected.

  An implementation in 2018–2020 as planned in the NAP, however, is not assured given the amount of funding and personnel available at the state (Länder) authorities responsible for the monitoring. At the same time, the Länder have called for the polluter pays principle to be enforced in the scope of funding. In order to achieve the quality objectives for all waters in the long term, however, it must be regularly verified whether the applicable Regulatory Acceptable Concentrations (RACs) for active PPP substances and their degradation products are in fact being adhered to in the approval process. Accordingly, for the planned small waters monitoring, the budgetary conditions must be created and open questions rapidly clarified between the Federal and Länder governments (in the areas of environment and agriculture).

- **Identifying risks and making information usable**
  In order to be able to better describe and assess the PPP-associated risks and effects on the organisms living in the waters, it is necessary to identify knowledge gaps regarding substances, their potential to spread and the potential to have side effects on the environment, and to act on new insights and take these into consideration in the approval process for plant protection products. It is essential to continue consistently implementing the strict approval process, with its precautionary principle, and to continually adapt the risk assessment methods.

  Data on the use of PPPs are especially important in the assessment of environmental risks. The problem at present, however, is that there is great difficulty in accessing this use data. The Federal Ministry of Food and Agriculture (BMEL), as the ministry responsible for plant protection, should ensure there is free access to existing use data and create a suitable framework – taking privacy into consideration – in order to make those records created as part of the compulsory documentation available to all stakeholders, including research, in the appropriate extent and timeframe.

6.4.2 Measures at the source and in use

- **Creating permanently green riparian buffer strips**
  Riparian buffer strips permanently covered with vegetation are a known measure for reducing the (diffuse) entry of pollutants into waters. Green buffer strips directly affect those small waters in the agricultural landscape that are especially important to the natural balance and which are most strongly affected by PPP pollution due to their proximity to the areas treated with PPPs and their low water volume. The NAP therefore already provides for 80 % of surface waters immediately adjacent to agriculturally used areas to be endowed with permanently green buffer strips by 2018, and 100 % by 2023. As a long-term Länder-specific goal, buffer strips without PPP usage shall be established along all surface waters of the agricultural landscape. A study on the status quo in 2010 revealed that, so far for the abovementioned surface waters, the average buffer strip width is only 1.9 m and that only 38 % of these water stretches had permanently green buffer strips of the 5-m target width provided for in the NAP.

  When creating new riparian buffer strips or expanding existing buffer strips, it is unavoidable that some arable land will have to be used. There are several conceivable ways to implement this. A binding nationwide regulation in the Federal Water Act (WHG) would be direct and comprehensively effective. Länder could also immediately enact stricter regulations in their water laws already using the escape clause to amend §38 WHG. Furthermore, farmers have the option to declare riparian buffer strips as “ecological focus areas”, funded through the Common Agricultural Policy (CAP) – Pillar I. A much stronger controlling effect could be achieved by ranking buffer strips higher as ecological focus areas (awarded more points than less effective measures for protecting the environment). Furthermore, creation of riparian buffer strips can be funded as an agri-environmental measure (CAP – Pillar II), for which the Länder would set corresponding funding focuses and the federal government should shift a larger portion of the funds from the first to the second pillar. This would require the reallocation share to be increased to the EU legal 15 %. The continued existence of this form of buffer strips on arable land is, however, only assured by permanently continued funding, public purchasing of land areas or expropriation. As a last resort, the plant health law could be applied to attach the use of PPPs to the condition of the presence of adequate riparian buffer strips.

  The implementation possibilities each include a synergistic effect on the entry of nutrients and suspended solids. In light of the options for action, there is above all a need for ample willingness on the part of politicians and the respective players.

- **Reducing the use of plant protection products**
  PPP pollution of waters depends greatly on the overall intensity of the chemical plant protection practiced in the real world. We need measures that reduce the use of plant protection products overall. The constantly rising figures for PPP sales emphasise this need for action. A successful recourse would be to abstain from using synthetic chemical plant protection products in favour of greater funding and propagation of organic agriculture and the (further) development of non-chemical control methods. The fact that, even four years after the NAP was introduced in 2013, only 6.5 % of arable

land is organically farmed is unacceptable. The federal and Länder governments are called upon to present adequate funding programmes and to eliminate the obstacles to their implementation.

Additionally, bans or **tighter restrictions of use in certain areas such as gardens and allotments**, in public greenery, in nature preserves or in water protection areas should be imposed, and voluntary abstinence at the local level (pesticide-free municipalities) should be supported and promoted. The players at the federal, Länder and local level have the power to act through authorisations in the Plant Protection Act; however, their action so far still lags behind their potential.

- **Setting and enforcing better standards**
  The better (technical) pollution reduction measures are established and implemented in standardised form, the more effectively water pollution will be reduced. Better **landscape structures and erosion-minimising cultivation techniques**, for example, could counteract any existing surface runoff on the arable land. The abovementioned permanently green riparian buffer strips have a complementary effect on this. Aside from these, we need to develop new, smart solutions in the scope of application technology dedicated to the minimisation of environmental exposure. However, we could already achieve a significant reduction of the total load in waters using the existing technology we have now, in particular by applying the best available techniques, e. g. by defining a **minimum standard for drift-reducing application techniques**. The Netherlands and Denmark are providing an example for us.

  Inconsistencies between water and plant protection regulations, for example in the handling of non-relevant metabolites that are increasingly proving to be problem substances in waters, must be eliminated. Denmark is also a forerunner in the **definition of threshold values**. Following the precautionary principle, the German federal and Länder governments should, together with the water suppliers, agree upon uniform guidelines for those substances as well that have (so far) not been ascribed any known (eco)toxicological potential.

Table 5

Assessment matrix of selected measures for plant protection products

Measures	Effectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
Creating permanently green riparian buffer strips	+	Br.	o	1	+
Increasing the percentage of organically farmed areas	+	Br.	o	1–2	+
Further limiting or preventing the use of PPPs in certain areas	+	Br.	o	2	+
Setting and enforcing better standards	+	Br.	o	1	+
Combining prospective risk assessment and monitoring	+	Spec.	o	2	+
Making spatially and temporally resolved data on the use of PPPs available	+	Br.	o	2	+
Eliminating deficits and assessment gaps in the approval and authorisation processes for plant protection products	+	Br.	+	1–3	+

Expected effect: (+ high), (o moderate), (spec. measure is substance-specific), (br. measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term ‹ 5 years), (2 = medium term ‹ 10 years), (3 = long term › 10 years)
Costs: (+ low), (o moderate), (- high)
Feasibility: (+ immediately feasible), (o not yet immediately feasible), (- still clear deficits/need for action (need for research, funding or acceptance))

Source: German Environment Agency (expert assessment)

Nearly all of the selected measures stand out for a high expected effectiveness over a broad spectrum of substances, which can be expected in mostly the short to medium term at low to moderate cost (Table 5). Nevertheless, there is still great resistance from most of the stakeholders of conventional agriculture that is largely oriented along chemical plant protection. Obstacles in the implementation of the measures are thus less due to the feasibility and more due to a lack of willingness within agricultural policies and among the respective players.

6.5 Biocides

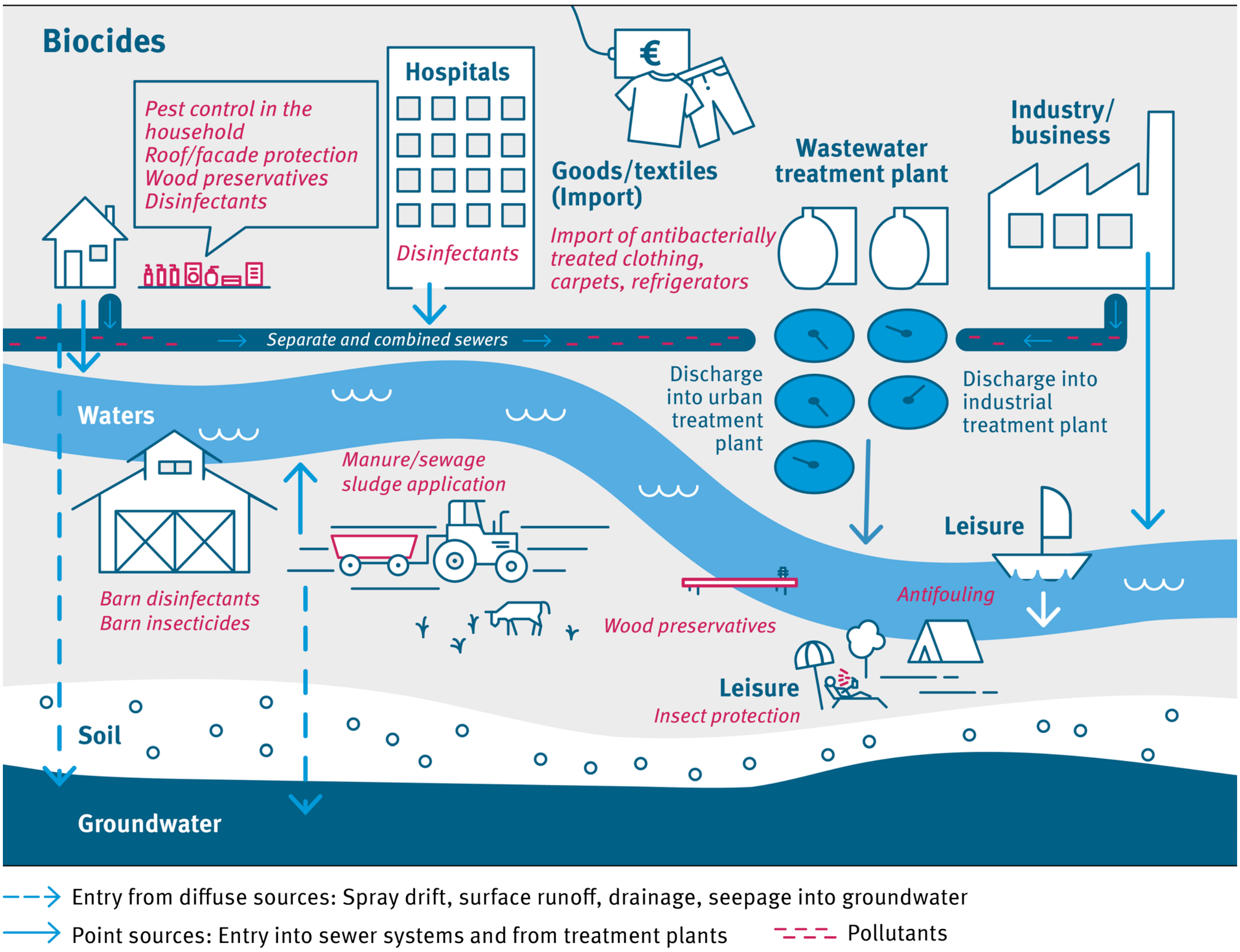
Biocides include pest control products (e.g. insecticides or rodenticides), disinfectants and material preservatives. Many products are used in the direct vicinity of humans, e.g. in the household. Due to the many applications, biocides get into the environmental media via many different entry pathways (Figure 6). However, because many active biocidal substances are also used in plant protection products, their presence in waters cannot be clearly attributed to any specific use.

A prominent example of biocides directly entering into surface waters is the release of active antifouling agents from ship paints. These substances can be highly toxic and thus harm aquatic ecosystems. Another special application of biocides that also results in direct entry into surface waters is extensive combatting of mosquitos on waters. Biocides are sometimes applied over wide areas for this purpose, often from helicopters.

In urban areas with a separate sewer system, various preservative substances are washed out from structures like building facades with rainwater and then washed directly into the connected waters, where treatment is typically limited to retention before the inlet into the sewer (e.g. trough-trench systems) or sedimentation in retention basins within the sewer system.

Figure 6

Schematic illustration of possible entry pathways of biocides into waters



Source: German Environment Agency

A large percentage of the biocides, however, makes it into the environment via indirect pathways. Indirect simply means these substances only reach waters or soil after going through an intermediate step. Most entry into water bodies is from treatment plants. It is known that very many biocides of various product types make enter treatment plants, especially disinfectants. If rainwater is collected in the combined sewer system of the urban area in question, then preservatives such as those used on building facades and roofs will also be introduced into the municipal wastewater. In heavy rainfall events resulting in overflowing rainwater, biocides can also be introduced into the surface waters directly with the wastewater.

Indirect entry of biocides into agriculturally used soil from manure occurs for disinfectants used for veterinary hygiene and for pest control products used in animal barns. After manure has been applied, the biocides or related transformation products it contains can be washed into surface waters with rain, or transported into deeper soil layers until they reach the groundwater.

At present, we can make no assertions regarding biocide loads in waters and the degree of environmental pollution. On the one hand, data regarding the sale and use of biocidal products in Germany and the EU are lacking, and on the other hand, there is no systematic monitoring practice for biocides in the environment. In the regime of the Water Framework Directive on the selection, analysis and monitoring of substances, biocides are included along with other substance groups. As a contribution to reducing micropollutant entry into waters, the overarching goal is to limit the use of biocides to the minimum that is strictly necessary and to reduce unnecessary environmental pollution by making the use of biocides as targeted as possible. Furthermore, biocide-free alternatives should also be promoted. Measures enforced by the European Biocidal Products Regulation (EU) No. 528/2012 are helping to achieve this goal (e. g. exclusion or substitution of substances of concern, risk-mitigation measures, restrictions on use and conditions for the authorisation of biocides). However, these measures do not, by a long way, exhaust all possibilities for reducing the entry of active substances into the environment. Accordingly, further measures must be developed, addressed and implemented that go beyond the existing regulations.

6.5.1 Creating and improving evaluation bases and criteria

- **Systematically recording and monitoring environmental pollution caused by biocides**
  Creating a broad knowledge base about emissions of biocides into the environment is indispensable for identifying reduction potentials and defining measures. The environmental pollution by biocides in Germany first has to be systematically recorded in various environmental media. This recording of the pollution situation can reveal the efficiency of existing measures or any further need for action, e. g. the specification of EQSs for biocides. Building upon a research project concluded in 2016 ("Development of cornerstones for a monitoring programme for the assessment of biocide emissions into the environment" [60]), a corresponding suggestion for a Germany-wide monitoring programme, including the prioritisation of relevant active biocidal substances, has already been developed by the UBA [61]. It is the responsibility of the federal states (Länder) to implement this measure (e. g. implementing in existing monitoring programmes or conducting monitoring campaigns). A regulation framework for Germany-wide monitoring would lead to the perpetuation and unification of monitoring.

6.5.2 Measures at the source

- **Establishing subordinate legislation**
  Prior experience in the approval of biocidal products shows there is a need for further regulation. It is necessary to define, in a body of subordinate legislation, legal specifications for expert appraisal, dispensation, good practices, the collection of sales and use data, requirements for equipment for biocide application, the protection of sensitive areas, and the prohibition of aerial application of biocides. This body of legislation is urgently needed in order to close existing regulation gaps and to be able to impose and implement risk reduction measures legally bindingly. The introduction of regulations on the dispensation of biocidal products would ensure that biocidal products that, for example, have only been authorised for expert users, as a way to ensure proper use, are in fact only dispensed to such experts. The first concepts for how this may be structured in content and form have already been developed; however, these have not yet been implemented by the legislators.

Legal specifications for expertise pose a similar opportunity. These would allow necessary expert appraisals to be defined for the use of certain biocidal products. This would clarify the conditions for restricting the user categories in the authorisations. At the same time, it would ensure that experts are in a position to use biocidal products as effectively as possible in a proper and environmentally friendly manner.

Collecting sales and use data (sales data) on active biocidal substances and biocidal products would allow a better estimation of the anticipated emissions and environmental pollution, the prioritisation of applications and active substances, and the derivation of targeted measures for reducing emissions. The legal bases for a regulation on data collection already exist (§12h (2) No. 2 of the German Chemicals Act (*Chemikaliengesetz*)). There is now an urgent need to implement this provision.

- **Abstaining from using antifouling products in sensitive areas**
  Another effective measure is to introduce a ban on antifouling products on boats in sensitive areas or nature preserves. The active substances from biocide-containing antifouling coatings on boats are directly emitted into the surrounding water. Therefore, in sensitive ecosystems or in protected areas, biocide-free alternatives ought to be used. The abstinence from using biocide-containing boat paints should be included in the protection provisions of the respective protected areas. The direct entry of biocides into waters in specially protected areas can thus be effectively prevented.

6.5.3 Measures in use

- **Education and communication**
  Biocidal products are often used by non-expert persons in private households. For this reason, educating the population is an important measure for ensuring responsible use of biocidal products. Apart from explaining the proper use of these products, this measure includes in particular educating the public about the unnecessary use of products and about possible biocide-free alternatives and/or preventive measures. This information is provided through the biocide portal www.biozid.info, among other places. It is necessary to continue expanding, updating, improving and conducting information campaigns in order to maintain the effectiveness of this measure and to reach new target groups.

- **Regulating requirements for equipment for applying biocides**
  Another example of a measure in use is to define specific requirements for the equipment used to apply biocides. For large-area spray application, in particular, low-drift equipment or optimised application practices can be used in order to reduce emissions into the environment.

Many of the suggested measures for biocides relate to creating national subordinate legislation (Table 6). The costs for manufacturers, distributors or users resulting from the specified requirements and the abstinence from using antifouling products in certain areas are difficult to estimate, but are gauged to be low to moderate. At this juncture, we cannot make any assertions as to the costs for surveys, since this depends on the extent to which they are performed. All measures relate to a broad spectrum of substances. The anticipated entry reductions by most of the measures can be achieved in the medium to long term. Measures for education and communication, however, promise earlier effectiveness.

6.6 Chemicals in the regulatory scope of REACH

The EU REACH regulation [62] applies to most technically produced substances whose use is not already covered by other legal regulations. This could be manufactured or imported ingredients or additives that are used in technical mixtures or products for professional users or consumers, such as in paints or adhesives, or in many other everyday products such as tyres, shoes, clothing or toys. These chemicals must be registered by the companies when used in quantities from 1 tonne per annum. Currently, these amount to 40,000 substances. For registration, data on the use patterns for these substances, as well as important properties and effects on humans and the environment, must be presented. In addition to REACH, those substances classified as hazardous are still listed independently of tonnages in the classification and labelling inventory (according to the CLP Regulation [63]). Currently, these amount to 114,000 substances.

Table 6

Assessment matrix of selected measures for biocides

Measures		Effectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
Creating subordinate legislation	Dispensation	+	Br.	+	2–3	+
	Expertise	+	Br.	o	2–3	+
	Good practices	+	Br.	o	2–3	+
	Regulating requirements for equipment for applying biocides	+	Br.	o	2–3	-
	Prohibiting aerial spraying of biocidal products	+	Br.	o	2	-
	Collecting sales and use data on active biocidal substances/biocidal products	+	Br.	o	2–3	+
Introducing a ban on using antifouling products in sensitive areas/ nature protection areas		+	Br.	o	2	+
Systematically recording and monitoring environmental pollution caused by biocides		+	Br.	n.d.	2-3	-
Education and communication: actively sensitising the population with regard to proper and sustainable use of biocidal products		+	Br.	+	1	+

Expected effectiveness: (+ high), (o moderate), (spec.: measure is substance-specific), (br.: measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term ‹ 5 years), (2 = medium term ‹ 10 years), (3 = long term › 10 years)
Costs: (+ low), (o moderate), (- high), (n.d. no data, uncertain),
Feasibility: (+ immediately feasible), (o not yet immediately feasible), (- still clear deficits/need for action (need for research, funding or acceptance))

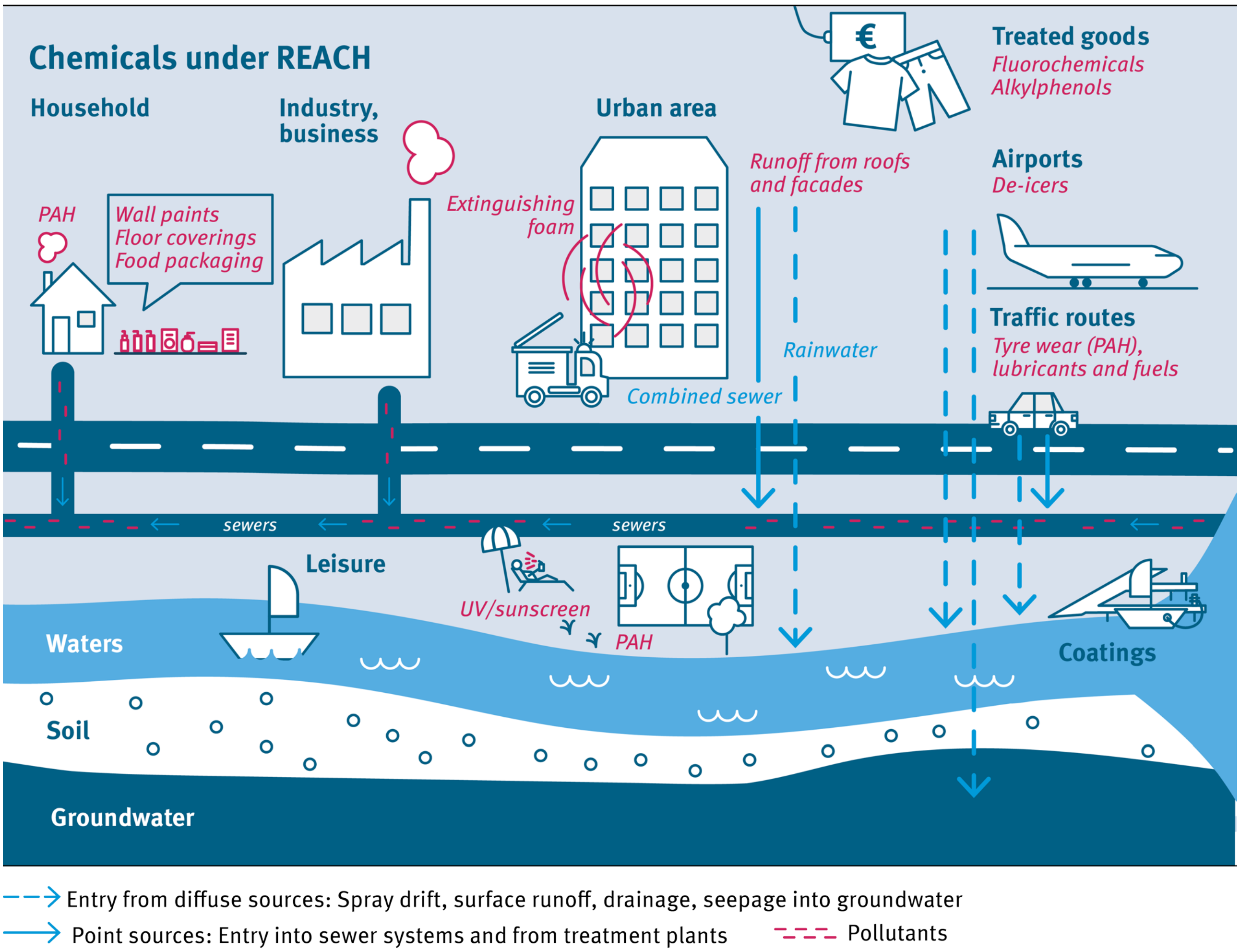
Source: German Environment Agency (expert assessment)

The objective of REACH is to achieve a high level of protection for man and the environment by applying the precautionary principle. Those companies that produce, import or otherwise use chemicals must guarantee safe use of those chemicals over their entire lifecycle. For hazardous substances from a tonnage of 10 tonnes per annum, registering companies must create a chemical safety report with an exposure assessment and, for this purpose, derive PNEC values [64] and the predicted environmental concentration (PEC) [51]. The most important information regarding the chemical must be communicated along the entire supply chain in the form of a material safety data sheet. All downstream users are obliged to manage all possible risks in the continued use of these chemicals. The authorities [65], in their turn, perform dossier and chemical evaluations as tools to ensure the necessary information on these chemicals does in fact exist. Substances that pose certain risks can be targetedly regulated, in particular, by limiting certain concentration ranges or uses, or by identifying substances of very high concern (SVHC) and potentially mandating subsequent authorisation to encourage substitution.

So far, some thousands of substances are subject to restrictions according to Annex XVII to the REACH regulation [66]. Currently, there are 173 entries [67] in the Candidate List of “substances of very high concern”, and 33 substances listed in the Authorisation List (Annex XIV). Europe-wide and river-basin-specific environmental quality standards for chemicals have been included in the list of priority substances of the Water Framework Directive (WFD) and its daughter directive 2008/105/EC, as well as the German implementation of the Surface Water Ordinance.

Figure 7

Schematic illustration of possible entry pathways of chemicals into waters



PAH polycyclic aromatic hydrocarbons

Source: German Environment Agency

Given the large number of substances and their different uses, the possible exposure pathways for surface waters are extremely varied (Figure 7). Exact loads cannot be stated. Chemicals can enter into water, soil and air during their manufacture, their processing or the rest of their product lifecycle, for example, either directly or indirectly via industrial and communal treatment plants or other routes of disposal. Besides emission from industrial and commercial applications (e. g. car workshops and building cleaning), chemicals from products (e. g. detergents, wall paints, textiles, toilet paper or packaging) used by consumers in the household can typically also make their way with the wastewater into the urban wastewater treatment plants and sewage sludge. These are point sources. In addition to these, there are many potential diffuse sources. In urban settlement areas, chemicals used professionally (e. g. aeroplane de-icers or extinguishing agents), released from buildings and building materials (e. g. insulators, insulating paints, roofs or artificial lawns), running off roads, airports or railways (e. g. tyre wear or anti-corrosion agents), from dumps or recycling processes (e. g. printer inks, colour developer or packaging), and from leisure activities (e. g. sunscreen UV filters or sports boats) can make enter into waters – also indirectly via rainfall. Chemicals also directly enter waters from use in the waterways (e. g. bulkheads, sheet piling and ships).

6.6.1 Improving evaluation bases and criteria

- **Improving data availability and communication**
  A study on behalf of UBA has shown that many of the registration dossiers submitted have deficiencies in the data [68]. Even if it is not clarified to what extent this has an actual influence on the safe use of substances, an improvement in data availability and forwarding along the supply chain is impor-

tant. This lies within the company's responsibility, and is followed up by the authorities.

- **Extending the REACH regulation instruments to imported products**
  The regulatory instruments for substances in products have serious deficiencies and allow only limited measures to be taken for imported products (restriction upon risk; if necessary a compulsory registration according to Art. 6 (5) REACH regulation). This should be improved during the upcoming revision of the REACH regulation.

6.6.2 Measures at the source

The possible regulations under REACH generally apply "at the source" and can only reduce substance pollution with the aim of avoiding risks.

- **Using the REACH instruments of authorisation/restriction to reduce emissions**
  The existing REACH instruments can be used to targetedly regulate substances that occur in waters as micropollutants.

  In the scope of authorisation and restriction, substances with properties of very high concern (SVHC)[69] can be identified in a special process (which takes 1–2 years) and then can be further regulated through an authorisation process or by restriction (see below) (which takes 4–7 years). When granting authorisation for substances subject to authorisation[70], there are conditions that can also apply explicitly to water pollution.

  Substances without SVHC properties that can be expected to pose risks due to the predicted concentration in the environment (PEC/PNEC > 1) can be regulated by restrictions[71] according to Annex XVII REACH (which takes 3–6 years). Restriction would also be possible for substances that exceed the EQSs in waters: In this way, binding threshold values could be defined for entry pathways into waters.

  There is a need for action to gain information on relevant micropollutants that could be used for substance-based legal processes. In the scope of substance evaluations under REACH, lacking information can be demanded from the companies.

  In this way, REACH can help to generate information on "unknown" substances for which we currently know nothing about their effects or use but which are found in water monitoring, or to learn of substances whose presence in waters should be analysed.

  A further improved interconnection of the REACH regulation with water legislation is important, even if certain parts of the REACH regulation already reference the Water Framework Directive and corresponding coordination mandates relating to the REACH regulation can already be found in the Environmental Quality Standards Directive (among others Article 7a).

- **Considering PMT substances as substances of very high concern**
  Substances critical to raw water that are simultaneously persistent, mobile in the water cycle and toxic (PMT) should be considered substances of very high concern in accordance with Art. 57 (f) REACH and, consequently, identified as SVHC. For this purpose, the UBA has had criteria and an evaluation concept developed in a study for better protection of drinking water, which can be used by companies and authorities[72]. The necessary information on use and substance properties already exists in the REACH registration dossier, and requires further evaluation. Possible representatives of PMT substances are, for example, per- and polyfluorinated chemicals, alkylphenols and benzotriazoles.

- **Using a realistic dilution factor for treatment plants in the exposure assessment**
  A current study[73] has shown that the dilution factor of 10 used as the standard for the exposure assessment for urban wastewater treatment plants is often too high, especially in low-water conditions. An adaptation of this treatment plant dilution factor (to preferably 1 to 2) would make the exposure assessment of the responsible regulatory authorities more realistic. As a result, the environmental risks of these substances would no longer be systematically underestimated, and potentially problematic applications could be identified. This can be used for monitoring conditions, for example, or for lowering the acceptable emission levels in chemical laws.

The above measures each need to be agreed upon with other member states or the European Commission.

Assuming a strong acceptance by the other Member States, the first two measures named above could be implemented in the short to medium term and become highly effective at low costs. The last named measure has a strong need for agreement at the EU level.

6.6.3 Measures in use

The risk reduction measures in production plants and processing operations are part of the safe use of chemicals throughout their lifecycle, and are therefore covered by "measures at the source" as a precaution. All downstream users must adhere to these bindingly. One further possible measure would therefore be better controls within operations or control of products, or stricter controlling of imported products for SVHC, which are also performed by the *Länder* authorities.

Currently, the REACH regulation includes neither a general mandate to minimise the entry of substances into the environment (beyond managing the risk), nor any requirements for implementing the principles of sustainable chemistry. These, too, are topics that the UBA will be promoting for the upcoming revision of the REACH regulation.

The first two of the suggested measures, which apply within the scope of REACH, are substance-specific (Table 7). The assessment of feasibility, costs and effectiveness therefore cannot be applied as blanket assessments; rather, they differ for each substance. A reduction of pollution can be expected within the medium to long term. Risk assessment measures and resulting reduction measures taken by companies, by contrast, can already become effective in the short to medium term. The measure regarding the dilution factor is not substance specific, and results in a general reduction of pollution due to the resulting reduction measures taken by the companies, depending however on the leeway (granted on the basis of the estimation model) in the risk or exposure assessment. All measures depend on agreement processes and acceptance at the EU level.

6.7 Detergents, cleaning products and cosmetics

The product group of washing detergents and cleaning products (detergents) and cosmetics are not subject to any particular authorisation. The European Regulation on Detergents (EC 648/2004) only regulates the ultimate aerobic biodegradation of surfactants that are used in private and commercial washing and cleaning detergents. The initially proposed regulation for anaerobic biodegradability of surfactants and for limiting the use of poorly degradable substances, however, has been struck. Furthermore, the German Detergent and Cleaning Products Act (*Wasch- und Reinigungsmittelgesetz*,

Table 7

Assessment matrix of selected measures for chemicals under REACH

Measures	Effectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
Using the REACH instruments of authorisation/restriction to reduce entry of individual substances that occur as micropollutants	n.d.	Spec.	n.d.	2–3	o
Avoiding the entry of substances critical to raw water into the environment in the regulatory scope of EU regulation REACH	+	Spec.	n.d.	2–3	o
Using a more realistic dilution factor for treatment plants in the exposure assessment of industrial chemicals	+	Br.	+	2	+

Expected effectiveness: (+ high), (o moderate), (n.d. uncertain because specific to substance, use or measures taken), (spec.: measure is substance-specific), (br.: measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term ‹ 5 years), (2 = medium term ‹ 10 years), (3 = long term › 10 years); usually depends on acceptance and agreement processes at EU level
Costs: (+ low), (o moderate), (n.d. uncertain because specific to substance, use or measures taken), (- high)
Feasibility: (+ immediately feasible), (o depends on acceptance at EU level), (- still clear deficits/need for action (need for research, funding or acceptance))

Source: German Environment Agency (expert assessment

WRMG) also regulates the primary degradability of surfactants from cosmetic products. When used as intended, detergents and cosmetics mainly make their way into treatment plants via the sewers (Figure 8). Nevertheless, direct entry into the waters as a result of overflowing combined sewers in heavy rainfall events is not to be neglected.

According to the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW), the annual entry of chemicals into wastewater resulting from private household detergents is approximately 530,470 tonnes (2015)[74]. These include:

- Surfactants (including soap): 184,419 tonnes
- Phosphates/phosphonates: 19,444/4,673 tonnes
- Perfumes: 9,027 tonnes
- Enzymes: 5,513 tonnes
- Optical lighteners: 434 tonnes
- Dyes and pigments: 109 tonnes

Adding to the previously mentioned entry of chemicals from private households are entries from industrial and business applications, for which less is known about their ingredients and quantities used, given that there is no systematic monitoring of this. Due to the large quantities that enter the wastewater, it must be assumed that surfactants also contribute to micropollutants, even though the Detergents Regulation prescribes their ultimate biological degradability.

One research project showed, for example, that linear alkylbenzene sulphonates (LAS) are found in Great Britain's waters at concentrations of up to 100 µg/l[75]. No data exists for Germany at present; however, one can assume the concentrations will be similarly high.

The recommended measures for reducing the entry of problematic detergent ingredients include conducting research projects on the presence of poorly degradable substances in the environment, creating an information system for problematic ingredients, running informative campaigns to educate the public on the sustainable handling of detergents, and the development of criteria for the eco-labels of detergents.

6.7.1 Creating and improving evaluation bases and criteria

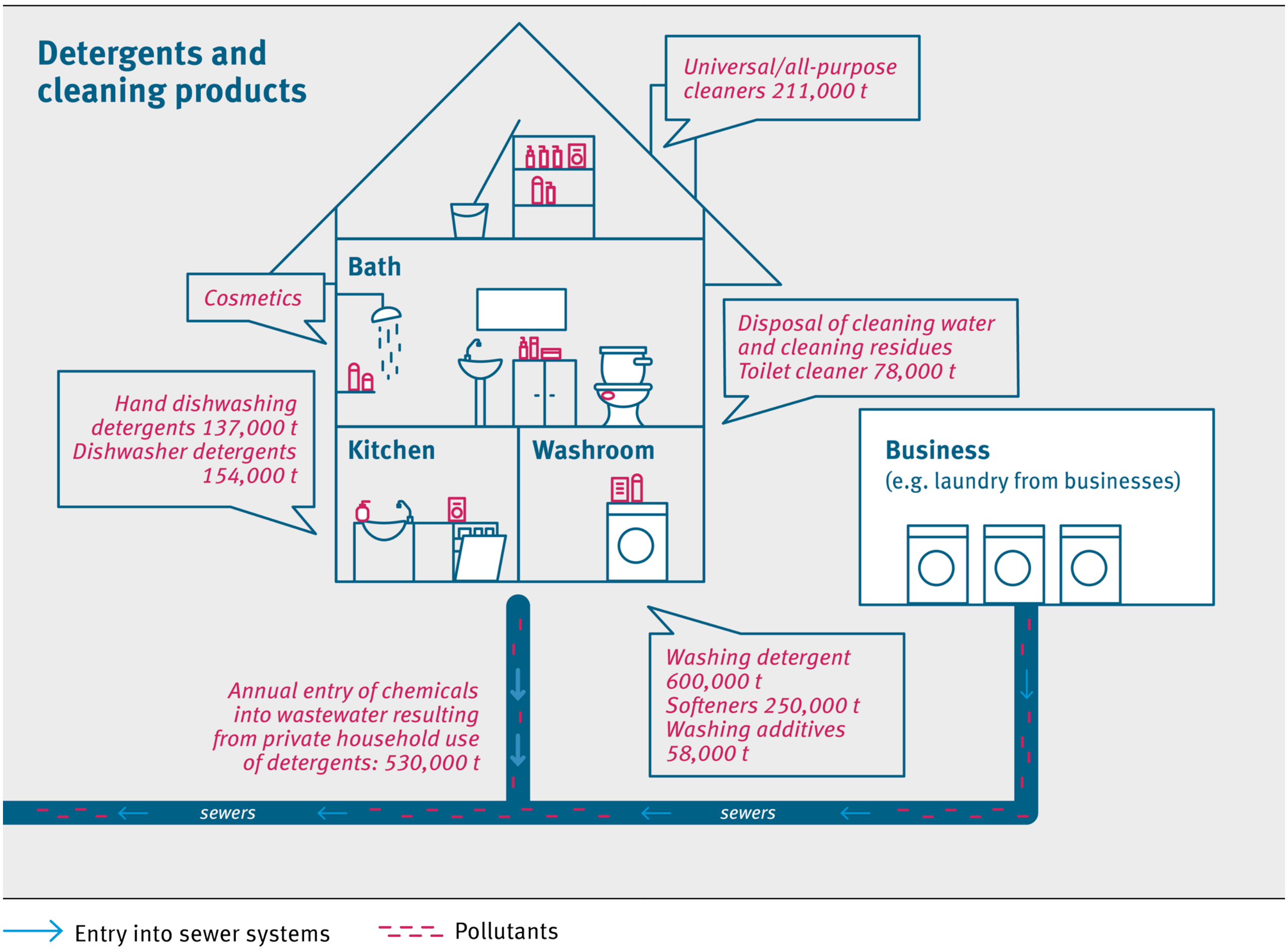
- **Researching the entry of poorly biodegradable substances from detergents into waters**
  There is a need for discussion on the restriction of poorly degradable substances and the development of analytical methods as prerequisite for a targeted monitoring. In the scope of one research project[76] performed by the UBA, various relevant substance groups have already been identified (e.g. fragrances and phosphonates).

  For the group of organophosphonates found in detergents in particular, the development of targeted analytical methods should provide insights into their persistence in the environment. Also problematic are the very large diversity of ingredients and the continuous new developments, at unknown tonnages and environmental behaviours. The substance group of optical brighteners, for example, accounts for various complex substances for which analytical methods are in part unavailable or expensive in their development and implementation.

- **Creating an information system for the ingredients of detergents**
  While a large proportion of the substances used in detergents are subject to compulsory registration under REACH, there is still often too little or nothing known about their environmental properties. In only very isolated cases are they included in water monitoring programmes (e. g. benzotriazole). Accordingly, further investigations on the presence of ingredients from detergents in waters are needed. First, the problematic ingredients from detergents that are relevant for monitoring must be identified. This requires, among other things, information on their toxicological relevance. In order to prioritise substances in future in terms of monitoring and possible restrictions, the UBA is currently building up its own public information system, which shall provide the necessary information about detergent ingredients by the end of 2018 at the latest.

Figure 8

Entry of detergents and cleaning products into wastewater



These data show the annual amounts of detergents used in private households in Germany (2013) and the resulting entry of chemicals into the wastewater

Source: German Environment Agency. Data: IKW (2017)

- **Enhancing the criteria for eco-labels for detergents**
  Products carrying eco-labels, e. g. "Blue Angel" (*Blauer Engel*) and "EU Ecolabel" are estimated to have a 10 to 15 percent market share. The respective eco-labels include provisions for limiting substance emissions from detergents during their use as well as for the biodegradability and classification of the ingredients. The authorities responsible for the eco-labels should, with the involvement of the product manufacturers, revise and tighten these criteria, in order to reduce the entry of harmful ingredients.

6.7.2 Measures at the source

Detergent manufacturers are legally obliged to only report the full formula, but without indication of quantities, to poison information centres and to the Federal Institute for Risk Assessment (BfR). This makes a systematic recording and analysis of substance emissions from detergents extremely difficult. Adding to this is a wide range of chemicals that are used in detergents, which is continuously widening due to new product developments. Nevertheless, according to REACH Annex XVII, certain substances, such as nonylphenols and nonylphenol ethoxylates, are forbidden or restricted for use in detergents. The German Environment Agency is continually verifying whether further ingredients could be concerned.

6.7.3 Measures in use

- **Information campaigns for sustainable handling of detergents**
  The existing PR work (e. g. flyers or interviews) on the sustainable procurement and use of detergents is continuously pursued. Joint initiatives with stakeholders from industry, science, authorities and consumer associations (e. g. FORUM WASCHEN and the Alliance for Sustainable Procurement) can provide additional information on more environmentally friendly alternatives of detergents. Furthermore, the German Environment Agency is continually updating its online material on sustainable washing and cleaning.

- **Information campaigns on the correct dosing of detergents**
  Greater efforts must also be made to reduce the unnecessary use of washing and cleaning detergents in the household area (e. g. from using too large doses). According to the UBA's estimates, washing detergents are used in excessive doses by the majority of consumers. If dosed properly, it is estimated, the amount of washing detergent could be reduced by approximately 20 %. The work done by a project group in the scope of the FORUM WASCHEN [77] for improving/simplifying the dosage of detergents must be continued, in the form of flyers and suitable dosing aids, in order to sensitise the population on correct dosage of detergents.

Aside from research into poorly biodegradable substances from detergents, which is hampered by high costs and low incentive, the measures are already being planned or implemented. The anticipated entry reductions resulting from these measures are mostly expected in the medium to long term.

7. End-of-pipe/overarching reduction measures

7.1 Fourth treatment stage

Relevance of municipal wastewater as an entry pathway

Municipal wastewater refers to household wastewater (wastewater from residential areas and corresponding services, predominantly of human origin) or a mixture of household and commercial wastewater including rainwater.

In Germany, around 10 billion cubic metres of municipal wastewater are produced per year, which must be treated in municipal treatment plants, after which it is released into surface waters. Of this, around 50 % is household and commercial wastewater, around 25 % rainwater and around 25 % infiltration water (e. g. infiltration into leaky sewers)[78]. Nearly 96 % of households in Germany are connected to sewer systems and thus to wastewater treatment plants. There are a total of around 9,600 public wastewater treatment plants in Germany.

More than 97 % of municipal wastewater is treated in a three-stage wastewater treatment process, involving mechanical, biological and chemical treatment[79]. The majority (around 90 %) of the municipal wastewater generated in Germany is treated in some 2,100 treatment plants of size categories (*Größenklassen*, GK) 4 and 5 with a capacity of greater than 10,000 PE (population equivalent)[80].

Municipal wastewater is a reservoir for many substances and, accordingly, also for micropollutants (Figure 9). The wastewater treated in municipal treatment plants is therefore the main entry pathway for many micropollutants into the waters. These substances and products originate, as mentioned above, from various different sources and applications, including among others: directly from households and businesses, indirectly via depositions from the air and traffic onto sealed surfaces, and as substances leached from buildings and washed into the sewer systems in rainfall events.

As water studies in Baden-Württemberg show, the average concentration of micropollutants often correlates with the proportion of wastewater in the waterbody[81]. A Germany-wide wastewater treatment plant monitoring effort will deliver further insights into the entry of priority substances from treatment plants[82].

Table 8

Assessment matrix of selected measures for detergents

Measures	Effectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
Researching the entry of poorly biodegradable substances from detergents into the waters	+	Spec.	-	3	-
Creating an information system for the ingredients of detergents	+	Spec.	o/+	2–3	+
Information campaigns for sustainable handling of detergents	+	Br.	+	2–3	+
Information campaigns on the correct dosing of detergents	+	Br.	+	2–3	+
Development of the criteria for eco-labels for detergents	o	Spec.	+	1–3	+

Expected effectiveness: (+ high), (o moderate), (spec.: measure is substance-specific), (br.: measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term ‹ 5 years), (2 = medium term ‹ 10 years), (3 = long term › 10 years)
Costs: (+ low), (o moderate), (- high)
Feasibility: (+ immediately feasible), (o not yet immediately feasible), (- still clear deficits/need for action (need for research, funding or acceptance))

Source: German Environment Agency (expert assessment)

The technologies used in municipal treatment plants are generally not designed for eliminating poorly biodegradable compounds (including micropollutants). Annex 1 “Household and municipal wastewater” of the Wastewater Ordinance (*Abwasserverordnung*, AbwV) so far includes no legal requirements for micropollutants.

Recommended measure

Only with the help of a suitable advanced (fourth or “quaternary”) treatment stage can a broad spectrum of anthropogenic micropollutants be removed [83].
A number of treatment plants, above all in North Rhine-Westphalia and in Baden-Württemberg, have already been outfitted with a fourth treatment stage. Other federal states (e. g. Berlin, Bavaria and Hesse) have plans for upgrading their treatment plants.

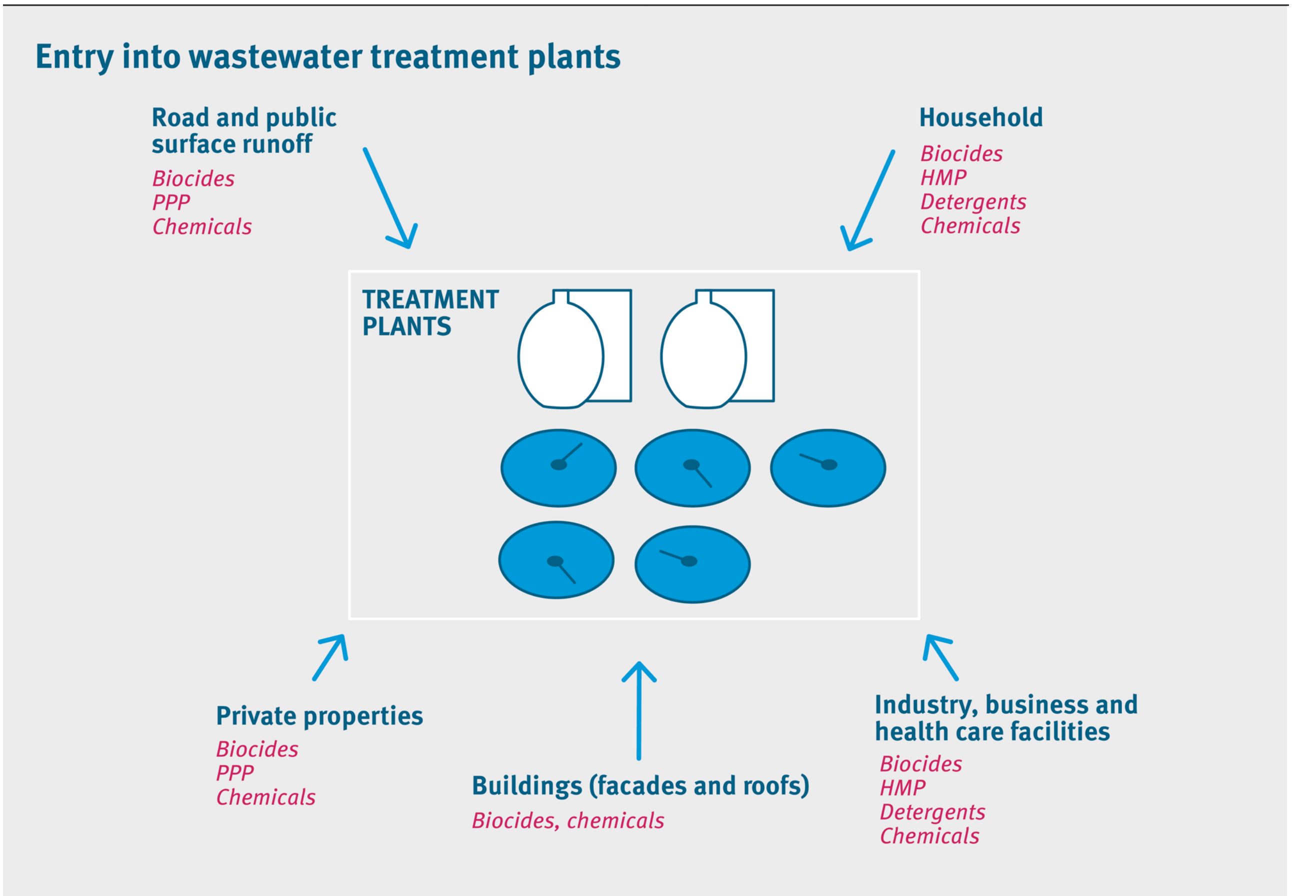
So far, in practice, two methods for advanced wastewater treatment have proven technically feasible on a large scale: oxidation with ozone and adsorption onto activated carbon (powdered or granulated activated carbon), or a combination of the two methods.

In an appropriately equipped treatment plant, a reduction by 80 % is possible for many micropollutants, where the degree of elimination is substance-specific and depends on the technology.

Both ozone and activated carbon require a post-treatment stage. Many of the reaction products resulting from ozonation can be reduced in a downstream biological stage, such as sand filters or biofilters, or in an adsorptive stage. In activated carbon treatment, downstream filtration, such as with a sand filter, largely ensures particle retention.

Figure 9

Schematic illustration of possible entry pathways of micropollutants into wastewater treatment plants



Point sources: Entry into wastewater treatment plants   Pollutants

HMP: Human medicinal products; VMP: Veterinary medicinal products; PPP: Plant protection products

Source: German Environment Agency

Both methods can achieve additional purification effects. These include, for example, reducing the content of organic substances or of phosphorus, or improving the hygienic quality of the effluent wastewater.

By expanding the 230 treatment plants of size category GK 5, 50 % of the total amount of wastewater in Germany could be treated and the total load of micropollutants that get into the surface water and oceans significantly reduced.

Compared to normal operation, operating advanced wastewater treatment leads to a 5–30 % higher energy consumption on average [84]. Depending on the size of the plant, the wastewater quality and the methods used, the energy requirement could also be higher. This must be taken into account in the assessment of the positive results of separating micropollutants and other substances out of wastewater. It must be pointed out, however, that many treatment plants still have considerable potential for energy savings or production.

In summary, the stepwise introduction of the fourth ("quaternary") treatment stage, starting with GK 5 scale plants and plants that discharge into sensitive waters and waters for drinking water usage, offers the possibility to remove a great number of micropollutants from the wastewater and to do justice to the protection requirements of sensitive waters and waters used to obtain drinking water. The expansion of municipal treatment plants would result in a considerable disburdening of waters.

If the mandatory introduction of advanced wastewater treatment for certain plants is to happen, the legal conditions must be created, such as changing Annex 1 to the Wastewater Ordinance (*Abwasserverordnung*, AbwV), specifying requirements for micropollutants and, if necessary, changing the Wastewater Charge Act (*Abwasserabgabengesetz*, AbwAG), or establishing other instruments by which the fourth treatment stage could be financed (see Chapter 8).

Based on experience with the introduction of nutrient elimination in the 1990s, implementing the fourth treatment stage within 10–15 years appears realistic – taking into account the funding issues to be clarified. In the interests of planning security for plant operators, however, the necessary fundamental decisions should be made as soon as possible.

7.2 Centralised and decentralised rainwater treatment

Relevance of entry pathways

The wastewater flowing from urban areas is largely transported though the sewer systems for treatment in the treatment plant and then discharged into surface waters. In addition to this, depending on the type of sewer system, there are other entry pathways in the case of rainfall:

- In combined sewer systems, untreated raw wastewater diluted by rainwater is washed out (i. e. discharged directly into the waters without any treatment, by-passing the treatment plant).
- In separate sewer systems, rainwater is discharged separately into the waters.

So far, no reliable information exists on how relevant combined sewer overflow is for the entry of micropollutants in terms of load. Compared to the much higher volumetric flow of regular wastewater discharges of conventional treatment plants, this entry pathway is estimated to be relatively low. It could become relevant, however, once the GK 5 category treatment plants have been upgraded with advanced wastewater treatment and the degree to which the substances of interest are eliminated is high. For certain substances, however, Hillenbrand et al. (2016) assert a high entry relevance from combined sewer overflows. PAH and nonylphenol, for example, enter the waters to a large extent via this pathway (32 % and 28 % of total entries, respectively) [85]. Currently underway are "Qualitative studies on combined sewer overflows in Bavaria" [86], in which the pollution levels of, among other things, PAH, plant protection products, biocides and medicinal products from combined sewer overflow discharges are being determined.

Studies on the pollution levels of rainwater in Berlin [87] have identified rainwater discharges from the separate sewer system as a significant entry pathway for micropollutants in addition to treatment plant discharges. In Berlin, according to the study, organic micropollutants are introduced with rainwater discharge in an order of 1 tonne per year. For most of the substances investigated in this project, their loads are similar in rainwater and wastewater. For PAHs and biocides, rainwater discharge was the main entry pathway.

Recommended measures
In order to reduce the entry of substances into waters, different technical measures according to the state of the art can be considered depending on the type of sewer system. It can be assumed that micropollutants can be retained. However, the respective effectiveness of the measures needs to be investigated more closely.

In some cases technical bodies of legislation for implementing the examples of measures listed below are available; however, no binding legal regulations are in place at present.

1. Intermediate storage and treatment of combined sewer discharges/overflows

- In storm overflow tanks, storage sewers and rainwater retention basis;
- By enabling sewer volumes above the "static" discharge limit;
- By sewer management measures for targeted enabling of storage volumes (e. g. in stormwater tanks, storage sewers and canals);
- With retention soil filters;
- By increasing combined sewer treatment in treatment plants.

2. Centralised treatment of rainwater

- Rainwater retention basins and retention soil filters
- Sedimentation in rainwater sedimentation tanks and inclined treatment plants

3. Decentralised treatment of rainwater

- Avoiding rain discharges by unsealing, seepage and evaporation
- Choice of treatment depending on degree of pollution, e. g. seepage through the inhabited soil zone if the degree of pollution is low

Pollution of rainwater should be avoided in the formation of runoff and by reducing possible sources of micropollutants (see Chapter 6). Also the construction of further facilities for seepage or storage and treatment of rainwater can contribute to reduce pollutant loads.

According to the Federal Water Act (*Wasserhaushaltsgesetz*, WHG), rainwater should be directed into a nearby water body by seepage, trickling off or mixing with wastewater (§ 55 par. 2). This concept has so far not been concretised by specific regulations in the Wastewater Ordinance (AbwV). National-level requirements for discharge of rainwater (in combined and separate sewer systems) are currently being discussed in a German Federal/Länder Workgroup.

7.3 decentralised wastewater treatment from health care facilities

Relevance of entry pathways

Nearly 20 % of the active pharmaceutical ingredients contained in municipal wastewater originate from health care facilities [88, 89] and around 80 % from households. The proportion of radiocontrast agents, certain antibiotics and cytostatics introduced from hospitals is higher.

Radiocontrast agents strictly should not enter the sewer system or wastewater, rather they should be removed separately, because only few compounds are eliminated even in the fourth treatment stage [90]. Radiocontrast agents are used roughly equally in hospitals and X-ray practices, which is why both health care facilities must be accounted for. In pilot projects, collection systems for direct use at the patient (urine bags) have been successfully tried and tested.

As comparative studies on the centralised and decentralised98 treatment of wastewater from health care facilities to eliminate micropollutants such as human medicinal products show, separate wastewater treatment only reasonable in isolated cases, i. e. at selected "hotspots" [91]. The research projects noPILLS [92] and Sauber+ [93] came to similar conclusions. No greater entry of medicinal product residues, toxic substances, antibiotic-resistant bacteria or genes from the health care facilities investigated were detected; although, this cannot be generalised. Each entry pathway must therefore be analysed separately, in order to derive the necessary measures.

Recommended measures

The entry of radiocontrast agents, certain antibiotics and cytostatics can be reduced by

1. Separate collection of urine in hospitals (and X-ray practices as necessary) using special sanitary technology (e. g. installing separation toilets),

2. Collection at the hospital bed (special collection containers), in X-ray practices and in the household area after medical application (urine bags) and

3. Disposal of unused radiocontrast agents from hospitals and X-ray practices via special collection systems.

Irrespective of the methods employed, the collected urine must be taken to a regulated disposal site – typically an incinerator. In the process, once special disposal logistics have been developed, iodine can also be recovered from the urine.

The measures for separate collection and disposal of radiocontrast agents should be performed as a routine in hospitals and X-ray practices. Ideally, the manufacturers of the radiocontrast agents should provide suitable urine bags together with their product.

The introduction of a 4th treatment stage stands out for high cost efficiency, due to the broad spectrum of micropollutants (Table 9) that could be reduced by this measure at reasonable cost (see Chapter 8). Its practical feasibility has been demonstrated by the upgrading of treatment plants, for example, in North Rhine-Westphalia and Baden-Württemberg [94]. The debate about implementing the "polluter pays" principle, i. e. about who shall bear the costs (financing), is proving a hindrance.

Measures for treating rainwater and combined sewer discharges are technically feasible. No concrete studies have been developed yet to investigate their effectiveness at retaining micropollutants. While the costs can be moderate for certain plants, depending on the technology, an estimate of the total cost for all of Germany requires further knowledge about the number of plants and financing models. The abovementioned projects have already delivered positive experience in the separate collection of radiocontrast agents but, ultimately, patients' acceptance will be an essential criterion for its implementation.

7.4 Industrial wastewater

Relevance of entry pathways

Micropollutants can also get into the waters out of emissions from industrial processes. A distinction must be made here between the manufacture and processing of chemical substances, e. g. in plants of the chemicals industry, and their use as chemical adjuvants in commercial and industrial operations. Both of these factors are relevant to our context. Operations that use chemical adjuvants include, for example, textile finishing companies, tanneries, electroplaters, paper factories and chip producers. Chemical adjuvants range from complexing agents, surfactants, preservatives, flame retardants,

Table 9

Assessment matrix of selected measures for wastewater

Measures	Effectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
Fourth treatment stage	+	Br.	o	2-3	+
Advanced centralised treatment of rainwater	o	Br.	o	2-3	+
Advanced decentralised treatment of rainwater	o	Br.	o	2-3	+
Advanced centralised treatment of combined sewer discharges	+	Br.	o	2-3	+
Separate collection/disposal of radiocontrast agents	+	Spec.	+	1-2	o

Expected effectiveness: (+ high), (o moderate), (spec.: measure is substance-specific), (br.: measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term ‹ 5 years), (2 = medium term ‹ 10 years), (3 = long term › 10 years)
Costs: (+ low), (o moderate), (- high) or cost effectiveness: (+ high), (o moderate), (- low)
Feasibility: (+ immediately feasible), (o not yet immediately feasible), (- still clear deficits/need for action (need for research, funding or acceptance))

Source: German Environment Agency (expert assessment)

anticorrosives, conditioners, solvents, wet strength agents and biocides to optical lighteners and dyes. Most of these substances are only used in commercial and industrial operations and not in private households.

Our knowledge regarding the type, number and quantity of active substances, their eliminability and importance as processing and production adjuvants in the respective industries is incomplete. The same applies to the type and quantity of industrial chemicals that get into the waters either directly or indirectly ("indirectly" means the industry does not discharge its wastewater directly into the waters, but into the sewer system, which then flows to a treatment plant with a biological treatment stage). Typically, from the multitude of possible pollutants or pollutant groups, assessments of micropollutants from industrial sectors only look at a few exemplary adjuvants in the form of preparations (formulations such as EDTA, PFOS, PFOA or nonylphenol) and estimate emission loads or substance entries into waters for those substances.

Existing measures
Micropollutants in industrial wastewater are regulated neither at the EU level nor at the national level under this term. They are, however, partially addressed indirectly by requirements for individual substances according to the best available techniques (BAT) in the EU, and the state of the art in Germany.

At the EU level, the Industrial Emissions Directive (IED) regulates the requirements for the construction, operation, and cessation of operations of industrial plants. Relatively large industrial operations require an EU-wide permit and must be operated according to BAT. BAT includes measures for reducing emissions in waters and, specifically, the use of less harmful feedstocks. As such, micropollutants are addressed under BAT. So far, however, the European BAT only address select measures that touch upon the topic of micropollutants (e. g. PFOS in the BAT Guidance Note on the Surface Treatment of Metals and Plastic Materials). In order to reduce micropollutants from wastewater discharges, one needs to actively use the information exchange on BAT at the EU level. BAT conclusions should also include requirements that lead to a reduction of emission of micropollutants. If this succeeds, then this will lead to emissions reductions in all EU Member States.

In Germany, minimum requirements for the introduction of wastewater into waters are specified in the Wastewater Ordinance (AbwV). Wastewater, the Ordinance decrees, may only be introduced into waters if the pollutant load is kept as low as is possible according to the state of the art. This includes the use of low-emission operating materials and adjuvants, as well as process-integrated recirculation and retention of substances. For every industry, minimum requirements for wastewater introductions are defined in a separate annex of the AbwV; it is through these that the wastewater-related BAT implications are enforced in Germany (see above). A number of these annexes to the AbwV already contain substance-specific requirements, such as prohibiting the drainage of certain undesirable substances with wastewater (zero emissions), or requirements for the substance properties (e. g. biodegradability or AOX content) of chemicals used. Pollutants that are not removable by conventional biological treatment plants must be removed already during operation by substitution or by suitable pretreatment (which also applies to operations that discharge into the sewer system). This leads to a reduction of the content of micropollutants in the discharged wastewater. Examples of substance-specific requirements in the annexes to AbwV are those used as finishing agents for textile finishing, organic complexing agents in the paper industry, or per- and polyfluorinated chemicals from the electroplating operations.

Emissions into soil and groundwater from industrial operations have been regulated by the provisions in the Ordinance on Facilities for Handling Substances Hazardous to Water (AwSV) since August 2017. The AwSV addresses substances that are hazardous to water generally without direct reference to potential micropollutants. It pursues the goal of zero emissions by applying multi-stage safety standards on the handling of substances hazardous to water. Based on Water Hazard Classes (*Wassergefährdungsklassen*, WGK) and substance quantities employed, technical and organisational requirements are defined that equate to a multi-barrier system (liquid-impervious storage containers and floors, detection systems, collection trays and, where applicable, proper disposal).

Recommended measures

In order to reduce the emission of micropollutants from industry and business, the UBA suggests the following measures:

- **Using potential synergies between EU directives that provide for measures to reduce the emission of micropollutants (HazBREF [95])**
  The aim must be to develop suitable BATs within the European process for determining emission-reduction measures for industrial emissions by targeted information management of substance data on industrial chemicals. These would then be implemented bindingly in the entire EU. The enforcement of measures to reduce the release of micropollutants in operations could be improved by reinforcing the interfaces between REACH, the Water Framework Directive and the Industrial Emissions Directive. For this purpose, the UBA initiated a project with 4 EU partner countries in the scope of the INTERREG *Baltic Sea Region Programme* 2017. This project (HazBREF) pursues the goal of deriving binding BAT conclusions also on substances whose use is regulated under REACH or which have been proposed for risk reduction measures (and for priority substances or substances on the WFD Watch List). The use of substance data and recommendations for risk management in the BAT process are being tested in example industries. At the same time, the results are being used to improve the regulation processes under REACH (registration, restriction and authorisation) using information from installation related legislation.

- **Initiating voluntary initiatives and stakeholder dialogues on the use of critical chemicals along the value chain in relevant industries**
  For the textile industry, a stakeholder dialogue is already ongoing in the *zero discharge of hazardous chemicals* initiative (ZDHC). This has set itself the goal to discontinue the use of certain chemicals in the entire production process. These include substances such as micropollutants, e. g. APOEs, flame retardants and per-/polyfluorinated compounds. The German "Partnership for Sustainable Textiles" also aims to avoid hazardous chemicals in the supply chain, and also follows the ZDHC. From these initiatives, a certain pressure to act is building up, above all, on international production plants. In the long term, this should allow micropollutant emissions to be prevented from the products as well. Further relevant manufacturer groups should initiate similar concrete, voluntary networks that act at the practical level, and thus promote the topic of "reducing micropollutants" in other industries as well.

- **Initiating projects in the departmental research plan (*Ressortforschungsplan*) for analysing the entry of micropollutants into the environment from industry and business and possible measures at the source**
  The first steps for developing and implementing targeted reduction measures are to compile and expand the existing knowledge on the sources, entry pathways and relevance of micropollutants from industry and business. Industries in which emissions of micropollutants can be expected should be systematically investigated by a project by the federal government in cooperation with the states (Länder) to determine what problematic substances are used, what emission loads are to be expected, and how these can be prevented or reduced. To this end, all available data and information sources should be used, including measurements in the wastewater of the operations, and if necessary in the drainage from municipal treatment plants and in the waters. Such a departmental research project allows the entry and importance of residual emissions from industry and business to be better categorised and knowledge gaps to be closed regarding the emitted substances and loads, as well as the techno-economic availability of the measures [96].

The recommended measures stand out for a high expected effectiveness over a broad spectrum at low cost (Table 10). HazBREF is a project for the analysis of interfaces. With regard to this project, as with the study on the enhancement of requirements in the Wastewater Directive (AbwV), the feasibility of reduction measures can only be assessed once the project is concluded. Efforts to *phase* out certain chemicals can be expected to meet with resistance from the manufacturers.

7.5 Overarching measures in agriculture

In agriculture, aside from the measures named in Chapter 6.4, there are overarching approaches that can reduce the entry of pollutants and thus reduce micropollutants in waters.

Expanding organic farming

Organic farming helps to achieve these goals by abstaining from use of synthetic chemical plant protection products and severe restrictions on the use of veterinary medicinal products [97]. Due to this and other positive environmental benefits of organic farming, its further expansion should be consistently supported and promoted. At a good six percent of the agricultural land in Germany used as organic farming land, Germany is still far from achieving the goal of 20 percent organic farming land in Germany as set by the federal government's national sustainability strategy [98].

Erosion-reduction measures

Generally, measures to reduce wind and water erosion can help to reduce the entry of pollutants into waters due to soil erosion from agricultural land. In addition to planting catch crops and undersown crops, these measures include soil-conserving farming practices, such as mulch and direct sowing or strip-till practice.

Creating riparian buffer strips where PPPs and fertilisers are excluded

In order to prevent plant protection products and fertilisers from getting into the waters, the worked land and adjacent environment should be kept separate from each other (see also 6.4.2). An effective measure to achieve this is to create permanently green riparian buffer strips (e. g. hedges, riparian buffer strips with shrubs and trees). For effective delineation, the use of PPPs on riparian buffer strips should be prohibited.

Table 10

Assessment matrix of selected measures for industrial wastewater

Measures	Effectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
HazBREF	+	Br.	+	2-3	-
Voluntary initiatives for phasing out certain chemicals	+	Br.	+	1-2	o
Research projects for systematically investigating relevant industries with regard to chemical additives for enhancing requirements in the Wastewater Ordinance (AbwV)	+	Br.	+	2-3	+

Expected effectiveness: (+ high), (o moderate), (spec. measure is substance-specific), (br. measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term ‹ 5 years), (2 = medium term ‹ 10 years), (3 = long term › 10 years)
Costs: (+ low), (o moderate), (- high)
Feasibility: (+ immediately feasible), (o not yet immediately feasible), (- still clear deficits/need for action (need for research, funding or acceptance))

Source: German Environment Agency (expert assessment)

Phasing out the agricultural use of sewage sludge
In 2015 in Germany, 24 % of the sewage sludge from municipal treatment plants was used agriculturally. Through this use, the substances – including micropollutants – adsorbed in the sludge are spread out into the environment.

Given the problematic entry of pollutants into the environment, the revision of the Sewage Sludge Ordinance (*Klärschlammverordnung*, AbfKlärV)[99] provides for a partial phasing out of the agricultural use of sewage sludge. Within a transitional period until 2027, sewage sludge from treatment plants < 100,000 EP may be used agriculturally, after which only sewage sludge from treatment plants < 50,000 EP may be used.

Until the use of sewage sludge on soils has been completely phased out, the pollutant limits should still be adapted in the Sewage Sludge Ordinance (AbfKlärV) and Fertiliser Ordinance (*Düngemittelverordnung*, DüMV). No substance-specific requirements relating to micropollutants have been formulated so far in the existing legislation (Sewage Sludge Ordinance or Fertiliser Ordinance). Furthermore, it must be verified whether micropollutants that have never been monitored, such as certain active pharmaceutical ingredients, need to be regulated by limits in the medium term.

7.6 Waste/medicinal product disposal

Improper disposal of waste can present a potential entry pathway for micropollutants into waters. In Germany, the responsibility for waste disposal lies with the municipalities and administrative districts. The recommendations for disposal routes differ according to the regionally established disposal structures.

Problematic waste from the household, which contains harmful substances and could contribute to the entry of micropollutants (e. g. plant protection products, chemical residues, solvents etc.) may not be disposed of in the ordinary household waste. This is indicated by the symbol of a crossed-out rubbish bin. Depending on the disposal structure, waste of this kind is either collected by mobile hazardous waste collectors (*Schadstoffmobile*) or is to be brought to collection sites for hazardous wastes or recycling centres[100].

The possible routes for disposing of unused medicines are household waste, mobile collectors, pharmacies or recycling centres. The various different regulations sometimes cause ignorance and uncertainty in the population and accordingly to improper disposal down the sink or toilet. In the scope of the support initiative Risk Management of Emerging Compounds and Pathogens in the Water Cycle (RiSKWa), a map of Germany[101] has been developed to inform the population of the existing recommendations at the city or county level. Overall, education regarding the disposal of hazardous wastes ought to be increased (see also 6.2 on medicinal products).

8. Financing

Measures for reducing micropollutants (for example provision of data, informational measures and campaigns, technical measures in the use of products, or advanced water treatment) cost money. Accordingly, discussions about the effectiveness of a measure are often overshadowed by the question of who shall bear the costs. It is the duty of foresighted, socially responsible environmental politics to distribute the financial burden, on the one hand, on a polluter-pays basis and, on the other hand, fairly between the producers, the water industry and the citizens. The decision of who shall bear the costs not only determines who has to contribute to a measure and how much, but also has steering effects and – especially when combined with informational measures – incentives that could lead directly and indirectly to further reductions of pollution.

First of all, the costs of the measures must be laid bare. For example, the costs of upgrading 230 large municipal treatment plants throughout Germany (size category 5 at approximately 50 percent of the nationwide annual amount of wastewater) over a period of 25 years are estimated at 10.4 to 10.9 billion Euro in total, which would equate to 415 to 435 million Euro in annual costs for the elimination of micropollutants, including post-treatment [102]. For other measures, such as substituting certain substances for others, the costs have so far been unquantifiable, and surely vary from one substance to another. In any case, each cost comparison must take into account how much the substance load can be effectively reduced by a given measure. Only then can a cost-benefit ratio be calculated.

The benefits of improving the condition of waters by reducing micropollutants cannot be directly quantified. Studies on the public benefits of micropollutants reduction measures show that beneficial effects are to be expected for bathing waters, aquatic organisms, food production, rainwater use and drinking water supply, while the state of knowledge on these effects, however, varies [103].

For individual measures within the manufacturers' sphere of responsibility during production and marketing – such as environmental risk assessments, increased research, labelling, data provision and industrial wastewater treatment – it is generally the manufacturers who carry the costs. Only for "extra-mandatory" measures taken by the manufacturers and distributors, such as large-scale informational and awareness-raising campaigns or educational initiatives, would one contemplate whether additional means from other sources could be made available for those measures.

Unlike regulatory law, with its mandates and prohibitions, the targeted use of financing instruments offers leeway on the part of the players involved. Incentives of this kind could have both short-term effects (such as substitution of micropollutants or relevant products with already available alternatives) and medium to long-term effects (such as research and development of new environmentally friendly approaches or substitutes). Accordingly, it would be advisable to develop suitably adapted levy models for the various pollution sources and applications of micropollutants (plant protection products, prescription or non-prescription medicines, biocides, detergents or hotspots at health establishments).

The concept of the "polluter" paying for the costs of reducing pollution is also advocated in the political arena, as for example in the Environment Ministers' Conference (*Umweltministerkonferenz* [104]) and the German Bundesrat [105]: both urge the federal government to ensure that manufacturers and marketers of medicinal products and active pharmaceutical ingredients contribute adequately to the costs of pollution reduction measures, and/or that they be included in the financial responsibility of removing micropollutants from the aquatic environment.

Studies on a potential framework for a levy for plant protection products [106] and medicinal products [107] as well as on adaptations of the Wastewater Charge [108] and its incentives for funding advanced purification technologies [109] have already laid important foundations for further discussion in expert circles.

Overall, it appears suitable to use the existing Wastewater Charge from the German Wastewater Charges Act (*Abwasserabgabengesetz*, AbwAG) to fund measures that will improve the wastewater infrastructure for better elimination of micropollutants. In § 13, the Wastewater Charges Act already stipulates that the revenues are to be used “for measures that serve to maintain or improve the quality of waters”. As one example, the plants built with a fourth treatment stage in North Rhine-Westphalia and in Baden-Württemberg so far have all used funds from the Wastewater Charges Act.

While it would generally be desirable to make legal regulations in the scope of the Wastewater Ordinance (*Abwasserverordnung*, AbwV) concurrently to updating the Wastewater Charges Act (AbwAG), this is not absolutely necessary. If an incentive system uses the Wastewater Charge – for example by levying a flat wastewater charge for discharing micropollutants but offering the possibility of exemption/reduction if certain efficiencies are reached as well as options for offsetting investment costs – this could greatly improve the precautionary protection of waters and our empirical experience with technologies for eliminating micropollutants, and thus promote the development towards a new state of the art.

9. Conclusion/Outlook

Dealing with water pollution is currently experiencing a revival. As our analytical methods improve, we are increasingly able to detect even the tiniest concentrations in water at increasingly early stages. Substances that could already have adverse effects on humans and the environment at such low concentrations are referred to as micropollutants. Many of these are already long-known, but we are also continually finding new ones. Early discovery of problematic substances has the advantage of allowing us to counteract them before it is too late. Even better, would be to prevent any micropollutants from getting into the environment in the first place, especially into the water cycle. This requires precautionary water protection policies that recognise and identify the problematic substance properties and subsequently implement a combination of measures at the source, in use and downstream (i.e. in sewage treatment). Micropollutants originate from a variety of sources. As such, there are many different approaches for taking precautionary prevention and reduction measures. Merely applying the “polluter pays” principle cannot substitute for searching for the most efficient combination of measures. Accordingly, there is no one single solution to the problem. Rather, all known measures must be evaluated in terms of their effectiveness, the targeted substance spectrum, the timeframe until effectiveness, costs, and feasibility in the real world.

These criteria cannot be estimated in advance for all measures: costs and effectiveness differ depending on the scope or level of their implementation; measures that address specific substances can differ depending on the substance properties; and measures that serve research and data collection often only yield the necessary insights once they have been completed.

The presented recommendations illustrate what we believe are the next steps to be taken, in line with the above stated criteria for measures to prevent and reduce pollution caused by medicinal products, plant protection products, biocides, chemicals (under REACH), detergents and cosmetics. The recommended measures are the already implementable components of a strategy that needs to be continuously developed further. A key success factor for such a strategy is the availability of data regarding the properties of substances and their effects on the environment as well as the methods for their detection. It requires a great deal more information than available so far, as well as more data transparency. We also need further efforts to monitor environmental pollution by the abovementioned substance groups on the basis of uniform criteria.

Many of the measures we have named will require lengthy preparation, while others can be implemented in the short term. As different substances flows assemble in the municipal wastewater, we still maintain that improving the state of the art and upgrading municipal treatment plants is a vital part of the whole strategy. Different is the question as to who will carry the costs for the measures, in particular for upgrading the treatment plants. The cost issue requires social discussion, to decide whether costs should be covered by those paying wastewater charges or whether, and if so how, other groups (like manufacturers of medicinal products and other branches) should make their contributions. First proposals for a solution to this have already been made.

Water pollution in the form of micropollutants with potentially adverse effects will not diminish over time. This can be attributed to certain demographic changes (an aging society consumes more medicine) and economic trends (industrial agriculture still uses large quantities of plant protection products). Therefore, the necessary measures should be taken as soon as possible if we are to avoid future damage and costly remedial measures. The aim is to underpin this strategy with a broad consensus among the stakeholders, so that everyone becomes committed within their scope of responsibility to take reduction measures and bear the costs. Wherever this does not happen voluntarily, it is the task of politics to exert the appropriate control using regulatory law or financial instruments. In order to increase acceptance, the problem and the possible solutions must be communicated to a wide audience. This paper seeks to contribute towards this.

10. Appendix – Overview of the selected measures

Substance-specific reduction measures for creating and improving evaluation bases and criteria, at the source and in use

Human medicinal products ▸ see 6.2

- Developing and harmonising risk-reduction measures within the authorisation process
- Researching environmentally friendlier active ingredients / dosage forms
- Communicating with and educating specific target groups
- Running information campaigns on the proper disposal of unused pharmaceuticals
- Monograph system for active pharmaceutical ingredients
- Considering widening the requirement for a prescription based on environmental concerns

Veterinary medicinal products ▸ see 6.3

- Developing and harmonising risk-reduction measures within the authorisation process
- Banning PBT/vPvB substances in veterinary medicinal products
- Researching environmentally friendlier active ingredients / dosage forms
- Communicating with and educating specific target groups
- Monograph system for active pharmaceutical ingredients
- Researching how modifying the right to dispense may potentially affect the use of veterinary medicinal products

Plant protection products ▸ see 6.4

- Creating permanently green riparian buffer strips
- Increasing the percentage of organically farmed areas
- Further limiting or preventing the use of PPPs in certain areas
- Setting and enforcing better standards
- Combining prospective risk assessment and monitoring
- Making spatially and temporally resolved data on the use of PPPs available
- Eliminating deficits and assessment gaps in the approval and authorisation processes for plant protection products

Biocides ▸ see 6.5

- Creating subordinate legislation on:
  - Dispensation
  - Expert appraisal
  - Good practices
  - Regulating requirements for equipment for applying biocides
  - Prohibiting aerial spraying of biocidal products
  - Collecting sales and use data on active biocidal substances/biocidal products
- Introducing a ban on using antifouling products in sensitive areas
- Systematically recording and monitoring environmental pollution caused by biocides
- Educating and communicating: actively sensitising the population with regard to proper and sustainable use of biocidal products

Chemicals in the regulatory scope of REACH ▸ see 6.6

- Using the REACH instruments of authorisation/restriction to reduce emissions of individual substances that occur as micropollutants
- Avoiding the entry of substances critical to raw water into the environment in the regulatory scope of EU regulation REACH
- Using a realistic dilution factor for treatment plants in the exposure assessment of industrial chemicals

Detergents and cleaning products ▸ see 6.7

- Researching the entry of poorly biodegradable substances from detergents into the waters
- Creating an information system for the ingredients of detergents
- Information campaigns for sustainable handling of detergents
- Information campaigns on the correct dosing of detergents
- Developing the criteria for eco-labels for detergents

End-of-pipe measures

Municipal wastewater and rainwater ▸ see 7.1–7.3

- Fourth treatment stage
- Advanced centralised treatment of rainwater
- Advanced decentralised treatment of rainwater
- Advanced centralised treatment of combined sewer discharges
- Separate collection/disposal of radiocontrast agents

Industrial wastewater ▸ see 7.4

- HazBREF
- Voluntary initiatives for phasing out certain chemicals
- Research projects for systematically investigating relevant industries with regard to chemical additives for enhancing requirements in the Wastewater Ordinance (AbwV)

Endnotes

1. COHIBA – Control of hazardous substances in the Baltic Sea region. Final summary report of the COHIBA project – How to control and manage hazardous substances in the Baltic Sea region? https://www.lung.mv-regierung.de/dateien/a3_cohiba_final_summary_report_2012.pdf

2. RiSKWa – Risk Management of Emerging Compounds and Pathogens in the Water Cycle, http://www.bmbf.riskwa.de/en_index.html

3. Relevance of Trace Organic Substances in Berlin's Stormwater Runoff, http://www.kompetenz-wasser.de/en/project/ogre-relevanz-organischer-spurenstoffe-im-regenwasserabfluss-berlins/

4. Strategy Micropoll, https://www.eawag.ch/en/department/eng/projects/abwasser/strategy-micropoll/

5. Hillenbrand et al. (2014): Measures to reduce micropollutant emissions to water (UBA-Texte 25/2014). (German) https://www.umweltbundesamt.de/publikationen/massnahmen-zur-verminderung-des-eintrages-von

   Hillenbrand et al. (2016): Measures to reduce micropollutant emissions to water: Phase 2 (UBA-Texte 60/2016). (German) https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_87_2014_mikroschadstoffe_summary.pdf

6. ICPR – International Commission for the Protection of the Rhine (2013): Strategy for micropollutants: Integrated assessment of micro-pollutants and measures aimed at reducing inputs of urban and industrial wastewater. Report No. 203. https://www.iksr.org/fileadmin/user_upload/DKDM/Dokumente/Fachberichte/EN/rp_En_0203.pdf

7. Kompetenzzentrum Mikroschadstoffe Nordrhein-Westfalen, http://www.masterplan-wasser.nrw.de/das-kompetenzzentrum/

8. Kompetenzzentrum Spurenstoffe Baden-Württemberg, http://www.koms-bw.de/

9. FOEN – Swiss Federal Office for the Environment (2015): Gewässerqualität: Revision der Gewässerschutzverordnung. https://www.bafu.admin.ch/bafu/de/home/themen/bildung/medienmitteilungen.msg-id-59323.html

10. UBA (ed.) (2015): Organische Mikroverunreinigungen in Gewässern. Vierte Reinigungsstufe für weniger Einträge. Position. Dessau-Roßlau. https://www.umweltbundesamt.de/publikationen/organische-mikroverunreinigungen-in-gewaessern

11. BMUB/UBA (ed.) (2017): Policy Paper: Recommendations from the multi-stakeholder dialogue on the trace substance strategy of the German Federal Government; to reduce trace substance inputs to the aquatic environment. http://www.bmu.de/fileadmin/Daten_BMU/Download_PDF/Binnengewaesser/spurenstoffstrategie_policy_paper_en_bf.pdf

12. BMU – Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (2017): Übereinkommen von Minamata über Quecksilber. http://www.bmub.bund.de/themen/gesundheit-chemikalien/chemikaliensicherheit/gesundheit-chemikalien-download/artikel/uebereinkommen-von-minamata-ueber-quecksilber/

13. UBA (2016): Mikroplastik: Entwicklung eines Umweltbewertungskonzepts. Erste Überlegungen zur Relevanz von synthetischen Polymeren in der Umwelt. Texte | 32/2016 https://www.umweltbundesamt.de/publikationen/mikroplastik-entwicklung-eines

14. Pseudo-persistent: Substances continuously consumed and discharged in large volumes that, despite relatively good degradability, are measured at relevant concentrations in the environment.

15. E. g. Rita Triebskorn (ed.) (2017): Weitergehende Abwasserreinigung – Ein wirksames und bezahlbares Instrument zur Verminderung von Spurenstoffen und Keimen im Wasserkreislauf. http://dx.doi.org/10.15496/publikation-15721

16. LAWA – Working Group of the Federal States on Water Issues (2016): Mikroschadstoffe in Gewässern. http://www.lawa.de/documents/Uml24-2016_20160126_LAWA_Bericht_Mikroschadstoffe_in_Gewaessern_final_207.pdf, A. et al. (2011): Bergmann, A. et al. (2011): Zusammenstellung von Monitoringdaten zu Umweltkonzentrationen von Arzneimitteln. UBA-Texte 66/2011. https://www.umweltbundesamt.de/sites/default/files/medien/461/publikationen/4188.pdf

    Bund/Länderausschuss für Chemikaliensicherheit (BLAC) (2003): Arzneimittel in der Umwelt – Auswertung der Untersuchungsergebnisse, Bericht an die 61. UMK. http://www.blac.de/servlet/is/2146/P-2c.pdf HELCOM (2017): HELCOM (2017): Pharmaceuticals in the aquatic environment of the Baltic Sea region. http://www.helcom.fi/Lists/Publications/BSEP149.pdf

17. UBA (2017): Waters in Germany: Status and assessment, https://www.umweltbundesamt.de/publikationen/waters-in-germany

18. Carvalho, R.N.et al. (2016): Monitoring-based Exercise: Second Review of the Priority Substances List under the Water Framework Directive, Directorate General Joint Research Centre

19. Carvalho, R.N.et al. (2015): Development of the first Watch List under the Environmental Quality Standards Directive. Directive 2008/105/EC, as amended by Directive 2013/39/EU, in the field of water policy. European Commission, Directorate General Joint Research Centre

20. Wenzel, A et al. (2015): Revision der Umweltqualitätsnormen der Bundes-Oberflächengewässerverordnung nach Ende der Übergangsfrist für Richtlinie 2006/11/EG und Fortschreibung der europäischen Umweltqualitätsziele für prioritäre Stoffe. On behalf of the Federal Environment Agency. Texte 47/2015. Dessau-Roßlau.

21. Summary dossier review_Ibuprofen-DRAFT-JRC-2015_v2.doc

22. UBA (2017): Waters in Germany: Status and assessment, https://www.umweltbundesamt.de/publikationen/waters-in-germany

23. LAWA (2015): Bericht zur Grundwasserbeschaffenheit – Pflanzenschutzmittel – Berichtszeitraum 2009 bis 2012

24. LAWA (2016): Mikroschadstoffe in Gewässern. http://www.lawa.de/documents/Uml24-2016_20160126_LAWA_Bericht_Mikroschadstoffe_in_Gewaessern_final_207.pdf, A. et al. (2011): Bergmann, A. et al. (2011): Zusammenstellung von Monitoringdaten zu Umweltkonzentrationen von Arzneimitteln. UBA-Texte 66/2011. https://www.umweltbundesamt.de/sites/default/files/medien/461/publikationen/4188.pdf

25. IAWR et al. (2013): Memorandum regarding the protection of European rivers and watercourses in order to protect the provision of drinking water, http://www.rheinenergie.com/media/portale/downloads_4/rheinenergie_1/trinkwasseranalyse/IAWR-Memorandum-2013.pdf

26. LAWA (2016): Mikroschadstoffe in Gewässern

27. LAWA (2016): Mikroschadstoffe in Gewässern

28. Evaluation from the point of view of health of the presence in drinking water of substances that are not (yet) possible or only partially possible to evaluate. Federal Health Bulletin – Health Research – Health Protection 2003 • 46:249–251. https://www.umweltbundesamt.de/sites/default/files/medien/376/dokumente/evaluation_from_the_point_of_view_of_health_of_the_presence_in_drinking_water_of_substances_that_are_not_yet_possible_or_only_partially_possible_to_evaluate_recommendation.pdf

29. European Commission (2015): Commission Implementing Decision (EU) 2015/495 of 20 March 2015 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D0495&from=EN

30. European Communities (2011): Guidance Document No. 27: Technical Guidance For Deriving Environmental Quality Standards. https://circabc.europa.eu/sd/a/0cc3581b-5f65-4b6f-91c6-433a1e947838/TGD-EQS%20CIS-WFD%2027%20EC%202011.pdf

31. Hillenbrand et al. (2014): Measures to reduce micropollutant emissions to water (UBA-Texte 25/2014)

32. For more information about MoRE (Modeling of Regionalized Emissions), see https://isww.iwg.kit.edu/english/MoRE.php

33. See Chapters 3.2 and 3.3 in: Hillenbrand et al. (2014): Measures to reduce micropollutant emissions to water (UBA-Texte 25/2014)

34. IMS Health (2013): MIDAS database. Frankfurt/Main Germany

35. Snape (2016): private communication

36. Project website: www.transrisk-projekt.de

37. EMEA (2006): Guideline on the environmental risk assessment of medicinal products for human use (EMEA/CHMP/SWP/4447/00)

38. Further information on environmental pollution by pharmaceuticals: UBA (2014): Pharmaceuticals in the environment – avoidance, reduction and monitoring. https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/pharmaceuticals_in_the_environment.pdf

39. BAH – German Medicines Manufacturers' Association (2017): Der Arzneimittelmarkt in Deutschland 2016. https://www.bah-bonn.de/bah/?type=565&file=redakteur_filesystem%2Fpublic%2FBAH_Zahlenbroschuere_2016_web.pdf

40. UBA (2017): Arznei für Mensch und Umwelt? Umsetzung der Empfehlungen des Handbuches Kommunikationsstrategien zur Schärfung des Umweltbewusstseins im Umgang mit Arzneimitteln – ein Beitrag zum nachhaltigen Umgang mit Arzneimitteln. Texte | 18/2017. https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2017-03-07_texte_18-2017_nachhaltiger-umgang-arzneimittel.pdf

41. UBA (2015): Leaflet on the proper disposal of pharmaceuticals. https://www.umweltbundesamt.de/publikationen/arzneimittel-nicht-in-die-toilette-spuele

UBA/bdew (2017): Explanatory film "Medikamente richtig entsorgen". https://www.youtube.com/watch?v=nLH6s5fPUDA

42. BVL (2017): https://www.bvl.bund.de/DE/08_PresseInfothek/01_FuerJournalisten/01_Presse_und_Hintergrundinformationen/05_Tierarzneimittel/2017/2017_09_11_pi_Antibiotikaabgabemenge2016.html

43. See the UBA topic site on veterinary pharmaceuticals for more information: https://www.umweltbundesamt.de/en/topics/soil-agriculture/ecological-impact-of-farming/pharmaceuticals

44. Data relating to animal populations/treatment weighting factor of the EMA. See EMA (2015): Sales of veterinary antimicrobial agents in 26 EU/EEA countries in 2013. http://www.ema.europa.eu/docs/en_GB/document_library/Report/2015/10/WC500195687.pdf. For percentage of pastured cattle see DESTATIS (2011): Agriculture, Forestry, Fisheries. Census of Agriculture 2010. Series 3, Book 6.

45. EMA (2000): Guideline on Environmental Impact Assessment For Veterinary Medicinal Products Phase I http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500004394 (VICH GL6)

EMA (2004): Guideline on Environmental Impact Assessment For Veterinary Medicinal Products Phase II http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500004393 (VICH GL38)

46. EMA (2012): Assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products. EMA/CVMP/ERA/52740/2012. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001506.jsp&mid=WC0b01ac058002dd37

47. Vidaurre et al. (2017): Konzepte zur Minderung von Arzneimitteleinträgen aus der landwirtschaftlichen Tierhaltung in die Umwelt. UBA technical brochure. http://www.umweltbundesamt.de/publikationen/konzepte-zur-minderung-von-arzneimitteleintraegen

48. EMA (2012): Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products. EMA/CVMP/ERAWP/409328/2010. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/03/WC500124187.pdf

49. Vidaurre et al. (2017): Konzepte zur Minderung von Arzneimitteleinträgen aus der landwirtschaftlichen Tierhaltung in die Umwelt. http://www.umweltbundesamt.de/publikationen/konzepte-zur-minderung-von-arzneimitteleintraegen

50. UBA (2015): Environmental risk of veterinary medicines. https://www.umweltbundesamt.de/publikationen/environmental-risk-of-veterinary-medicines

51. https://www.umweltbundesamt.de/en/topics/soil-agriculture/ecological-impact-of-farming/pharmaceuticals

52. BMG (2017): DART 2020 – German Antibiotic Resistance Strategy. https://www.bundesgesundheitsministerium.de/themen/praevention/antibiotika-resistenzen/antibiotika-resistenzstrategie.html

53. UBA (2017): Waters in Germany: Status and assessment, https://www.umweltbundesamt.de/publikationen/waters-in-germany

54. BMEL (2013): National Action Plan on Sustainable use of Plant Protection Products. https://www.nap-pflanzenschutz.de/en/

55. Szöcs E. et al. (2017): Large scale risks from pesticides in small streams, Environmental Science & Technology. http://pubs.acs.org/doi/abs/10.1021/acs.est.7b00933

56. BVL (2016): Report on domestic sales and exports of plant protection products. https://www.bvl.bund.de/EN/04_PlantProtectionProducts/01_ppp_tasks/02_ppp_AuthorisationReviewActSub/03_ppp_DomesticSalesExport/PPP_domesticSales_and_Export_node.html

57. BMEL (2013): National Action Plan on Sustainable use of Plant Protection Products. https://www.nap-pflanzenschutz.de/en/

58. UBA (2016): 5-point programme for sustainable plant protection. https://www.umweltbundesamt.de/publikationen/5-point-programme-for-sustainable-plant-protection-0

59. SRU (2016): Environmental Report 2016: An integrative approach to environmental policy, https://www.umweltrat.de/SharedDocs/Downloads/EN/01_Environmental_Reports/2016_05_Environmental_Report_summary.pdf. (German) ISBN 978-3-503-167708, Erich Schmidt Verlag, Berlin

60. UBA-Texte 24/2017: Development of cornerstones for a monitoring programme for the assessment of biocide emissions into the environment. https://www.umweltbundesamt.de/publikationen/development-of-cornerstones-for-a-monitoring

61. UBA-Texte 15/2017: Are biocide emissions into the environment already at alarming levels? Recommendations of the German Environment Agency (UBA) for an approach to study the impact of biocides on the environment. https://www.umweltbundesamt.de/publikationen/are-biocide-emissions-into-the-environment-already

62. Regulation (EC) No. 1907/2006, aka REACH (Registration, Evaluation, Authorisation & Restriction of Chemicals)

63. Regulation (EC) No. 1272/2008, aka CLP Regulation (Classification, Labelling and Packaging)

64. PNEC: predicted no-effect concentration; PEC: predicted environmental concentration; Risk = PEC/PNEC.

65. The authorities involved in the regulatory measures of the REACH regulation include the responsible authorities of the EU Member States, the European Chemicals Agency (ECHA) and the EU COMMISSION

66. Most concern group entries, i. e. prohibiting the marketing of CMR substances in mixtures and substances for the general public, or excluding the use of substances of certain hazard classes in decorative objects, joke articles and toys. Further restrictions of substances and substance groups exist for approx. 100 substances, e. g. under consideration of the (formerly) economically relevant substances.

67. Certain entries include substance groups, so the actual number of substances is higher.

68. UBA (2015): REACH Compliance: Data Availability of REACH Registrations – Part 1: Screening of chemicals › 1000 tpa, Texte | 43/2015. https://www.umweltbundesamt.de/publikationen/reach-compliance-data-availability-of-reach

69. Criteria for classification as SVHC are presented in Article 57 of the REACH Regulation. For the environment, these are: PBT (persistent, bioaccumulative and toxic), or vPvB (very persistent and very bioaccumulative), or endocrine disruptive (ED)

70. The substances subject to authorisation are listed in Annex XIV of REACH.

71. Limitations for substances or substance groups are listed in Annex XVII of REACH.

72. Kalberlah, F. (2014): Guidance for the precautionary protection of raw water destined for drinking water extraction from contaminants regulated under REACH. Forschungs- und Beratungsinstitut Gefahrstoffe. Freiburg im Breisgau. UFOPLAN FKZ 371265416. For more information see https://www.umweltbundesamt.de/mobile-chemikalien

73. Link, M., von der Ohe, P.C., Voß, K. & Schäfer, R.B.: Comparison of dilution factors for German wastewater treatment plant effluents in receiving streams to the fixed dilution factor from chemical risk assessment; Science of the Total Environment 598 (2017) 805–813. doi: http://dx.doi.org/10.1016/j.scitotenv.2017.04.180

74. IKW (2017): Bericht Nachhaltigkeit in der Wasch-, Pflege- und Reinigungsmittelbranche in Deutschland 2015 – 2016. https://www.ikw.org/fileadmin/ikw/downloads/Haushaltspflege/HP_Nachhaltigkeitsbericht__15_16.pdf

75. Andrew Johnson et al. (2017): “An alternative approach to risk rank chemicals on the threat they pose to the aquatic environment”, Science of the Total Environment 599–600, 1372–1381. http://dx.doi.org/10.1016/j.scitotenv.2017.05.039

76. Öko-Institut (2012): “Untersuchung der Einsatzmengen von schwer abbaubaren organischen Inhaltsstoffen in Wasch- und Reinigungsmitteln im Vergleich zum Einsatz dieser Stoffe in anderen Branchen im Hinblick auf den Nutzen einer Substitution”. FKZ: 3709 65 430. http://www.bmub.bund.de/fileadmin/Daten_BMU/Pools/Forschungsdatenbank/fkz_3709_65_430_wasch_und_reinigungsmittel_bf.pdf

77. http://www.forum-waschen.de

78. Federal Statistical Office (2013): Öffentliche Wasserversorgung und öffentliche Abwasserentsorgung, Öffentliche Abwasserbehandlung und -entsorgung. Fachserie 19, Series 2.1.2. https://www.destatis.de/DE/Publikationen/Thematisch/UmweltstatistischeErhebungen/Wasserwirtschaft/AbwasserOeffentlich2190212139004.pdf

79. Federal Statistical Office (2013): Öffentliche Wasserversorgung und öffentliche Abwasserentsorgung – Strukturdaten zur Wasserwirtschaft, Fachserie 19, Series 2.1.3. (See prev. endnote for link)

80. Federal Statistical Office (2013): Öffentliche Wasserversorgung und öffentliche Abwasserentsorgung, Öffentliche Abwasserbehandlung und -entsorgung. Fachserie 19, Series 2.1.2. (See prev. endnote for link)

81. Ministry of the Environment, Climate Protection and the Energy Sector Baden-Württemberg Stuttgart; LUBW Landesanstalt für Umwelt, Messungen und Naturschutz Baden-Württemberg (2014): Messungen und Naturschutz Baden-Württemberg; Karlsruhe, Spurenstoffinventar der Fließgewässer in Baden- Württemberg. http://www.lubw.baden-wuerttemberg.de/servlet/is/243039

82. Germany-wide monitoring of treatment plants for priority substances is financed through the Länder and technically assisted/coordinated by the UBA. Results are expected in 2018/2019.

83. UBA (ed.) (2015): Organische Mikroverunreinigungen in Gewässern. Vierte Reinigungsstufe für weniger Einträge. Position. Dessau-Roßlau. https://www.umweltbundesamt.de/publikationen/organische-mikroverunreinigungen-in-gewaessern

84. UBA (2015): Organische Mikroverunreinigungen in Gewässern – Vierte Reinigungsstufe für weniger Einträge. (See previous endnote)

85. Hillenbrand et al. (2016): Measures to reduce micropollutant emissions to water: Phase 2 (UBA –Texte 60/2016). (German) https://www.umweltbundesamt.de/publikationen/massnahmen-zur-verminderung-des-eintrages-von-1

86. KIT: Qualitative Untersuchungen von Mischwasserentlastungen in Bayern. https://isww.iwg.kit.edu/english/607_2056.php

87. Wicke, D.; Matzinger, A.; Rouault, P. (2015): Relevanz organischer Spurenstoffe im Regenwasserabfluss Berlins. Pub. Kompetenzzentrum Wasser Berlin. Final Report, http://www.kompetenz-wasser.de/wp-content/uploads/2017/11/abschlussbericht_ogre_final_rev2.pdf

88. Adamczak, K., Lyko, S., Nafo, I., Evenblij, H., Cornelissen, E., Igos, E., Klepiszewski, K., Venditti, S., Kovalova, L., McArdell, C., Helwig, K., Pahl, O., Barraud, O., Casellas, M., Dagot, C., Maftah, C., Ploy, M.-C., Stalder, T. and PILLS (2012): Pharmaceutical residues in the aquatic system – a challenge for the future – Insights and activities of the European cooperation project PILLS. http://www.pills-project.eu/content/136/documents/PillsBrochure-de.pdf

89. Seidel, U., Ante, S., Börgers, A., Herbst, H., Matheja, A., Remmler, F., Sayder, B. and Türk, J. (2013): Analyse der Eliminationsmöglichkeiten von Arzneimitteln in den Krankenhäusern in NRW (TP 3), Landwirtschaft, Natur- und Verbraucherschutz des Landes Nordrhein-Westfalen (MKULNV), AZ IV-7 – 042 600 001C, Vergabenummer 08/0581. https://www.lanuv.nrw.de/fileadmin/forschung/wasser/klaeranlage_abwasser/131231_Abschlussbericht%20TP%203_Final_lang.pdf

90. Pinnekamp, J., Palmowski, L. und Kümmerer, K. (ed.) (2015): Abwasser aus Einrichtungen des Gesundheitswesens – Charakterisierung, Technologien, Kommunikation und Konzepte, Gesellschaft zur Förderung der Siedlungswasserwirtschaft an der RWTH Aachen (Facilities investigated: general hospital with clinics of orthopaedic, surgical and oncological focus, one psychiatric clinic and one nursing and care home)

91. Pinnekamp, Palmowski et al. (2015) (See previous endnote)

92. http://www.no-pills.eu/conference/BS_NoPills_Final%20Report_summary_EN.pdf

93. http://www.riskwa.de/en_1282.html

94. Kompetenzzentrum Spurenstoffe BW. http://www.koms-bw.de/en/

95. Kompetenzzentrum Mikroschadstoffe Nordrhein-Westfalen, http://www.masterplan-wasser.nrw.de/das-kompetenzzentrum/

96. HazBREF: http://www.syke.fi/projects/hazbref

97. A project on potential substitutions of PFOS in electroplating operations and a project on reducing the entry of micropollutants from wastewater out of CP treatment plants have been appointed for hazardous wastes in waters for the departmental research plan (Ressortforschungsplan) 2017.

98. Regulation EC No. 834/2007 and implementation regulation No. 889/2008 as EU basis for ecological production

Federal Statistical Office (2017): Nachhaltige Entwicklung in Deutschland. Indikatorenbericht 2016, p. 14. https://www.destatis.de/DE/Publikationen/Thematisch/UmweltoekonomischeGesamtrechnungen/Umweltindikatoren/IndikatorenPDF_0230001.pdf?__blob=publicationFile

99. Sewage Sludge Ordinance (AbfKlärV) from 15 April 1992 (BGBl. I p. 912), last amended by Article 74 of the Ordinance from 31 August 2015 (BGBl. I p. 1474). Verordnung zur Neuordnung der Klärschlammverwertung, Bundestagsdrucksache 18/12495 from 24 May 2017.

100. UBA (2014): Abfälle im Haushalt, Vermeiden, Trennen, Verwerten. Guidebook. https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/uba_abfall_web.pdf

101. Arzneimittel-Entsorgung richtig gemacht! http://www.arzneimittelentsorgung.de/

102. Hillenbrand et al. (2016): Measures to reduce micropollutant emissions to water – Phase 2. UBA-Texte 60/2016, p. 24 and 158 ff. (German) https://www.umweltbundesamt.de/sites/default/files/medien/377/publikationen/mikroschadstoffen_in_die_gewasser-phase_2.pdf

103. For details see Hillenbrand et al. (2016): Measures to reduce micropollutant emissions to water – Phase 2. UBA-Texte 60/2016, p. 176 ff. (German) https://www.umweltbundesamt.de/sites/default/files/medien/377/publikationen/mikroschadstoffen_in_die_gewasser-phase_2.pdf

104. Resolution minutes of the German federal Ministers of the Environment 80th conference on 7 June 2013 in Oberhof, TOP 18, No. 3. https://www.umweltministerkonferenz.de/documents/gesamt_umk_1522235976.pdf

105. Bundesrat, Paper 627/15 (Decision), p. 16 (Annex: B Resolution 3). (German) https://www.bundesrat.de/SharedDocs/drucksachen/2015/0601-0700/627-15(B).pdf?__blob=publicationFile&v=1

106. Möckel et al. (2015): Einführung einer Abgabe auf Pflanzenschutzmittel in Deutschland. ISBN 978-3-428-14800-4; Handout at: https://www.ufz.de/export/data/global/86986_Zusammenfassung_Gutachten.pdf

107. Gawel et al. (2017): Arzneimittelabgabe – Inpflichtnahme des Arzneimittelsektors für Maßnahmen zur Reduktion von Mikroschadstoffen in Gewässern, UBA-Texte 115/2017, https://www.umweltbundesamt.de/publikationen/arzneimittelabgabe-inpflichtnahme-des-arz

108. Gawel et al. (2014): Reform der Abwasserabgabe: Optionen, Szenarien und Auswirkungen einer fortzuentwickelnden Regelung. UBA Texte, 55/2014. https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_55_2014_reform_der_abwasserabgabe.pdf

109. Gawel et al. (2015): Mikroverunreinigungen und Abwasserabgabe, UBA-Texte 26/2015. https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_26_2015_mikroverunreinigungen_und_abwasserabgabe_1.pdf

▸ **This brochure as download**
bit.ly/2dowYYI

www.facebook.com/umweltbundesamt.de
www.twitter.com/umweltbundesamt
www.youtube.com/user/umweltbundesamt
www.instagram.com/umweltbundesamt/