Systemic Risk Governance for Pharmaceuticals Residues in Drinking Water
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Systemic Risk Governance for Pharmaceutical Residues in Drinking Water

Abstract
Pharmaceuticals are in many cases an indispensable element of a comfortable and healthy life. Nevertheless, there is also a downside to the widespread and increasing use of drugs: the occurrence of their residues in the aquatic environment and in drinking water. Although there is evidence for negative effects of active pharmaceutical ingredients (APIs) in some animal and plant species, it has not yet been shown which risks in fact exist for humans and the environment. At the same time there is evidence that people will reject drinking water which contains only the smallest traces of APIs, despite claims that such traces are harmless. In this mélange of high uncertainties, subjective risk perception, and the undisputed societal benefit of pharmaceuticals, established risk management procedures are likely to fail. Addressing this issue, the article will suggest applying the concept of systemic risk to the case of APIs in drinking water. With this concept as basis a practical approach to risk management will be presented. It draws upon the recently developed concept of risk governance, as well as the precautionary principle. Finally, concrete measures for risk precaution in the spheres of drug development, handling of drugs, and technical emissions control in urban water management will be presented.

Keywords
drinking water, drug development, health-care system, pharmaceutical, precautionary principle, risk governance, systemic risk, urban water management

In recent years systemic risks have been discussed as a new type of risk for which established risk management procedures are no longer applicable. These procedures fail because large-scale, highly interconnected systems are particularly vulnerable to “systemic events” – events that might trigger a sequel of mutually reinforcing destabilising processes for which containment fails, leading to extreme cases of damage (OECD 2003). Common examples of such events are natural catastrophes, accidents, terror attacks, human failure, or the instability of crucial system components. What this perspective ignores, however, is that it is often decentralised, intentional processes and cycles in a system which lead to a systematic, cumulative production of hazards. Producing energy by burning fossil fuels is but one prominent instance of the systematic production of an extreme hazard, namely, global climate change. Another such example is the widespread and increasing use of pharmaceuticals and its possible impacts on ecosystems and human health.1

Pharmaceutical Residues in Waters
The occurrence of pharmaceutical residues in drinking water is mainly an unintended side effect of their normal use. In order

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1 The results presented here were developed in the context of the joint research project start (Strategien zum Umgang mit Arzneimittelwirkstoffen im Trinkwasser, in English: Management Strategies for Pharmaceuticals in Drinking Water). start was funded from October 2005 until May 2008 by the German Ministry for Education and Research (contract number 07VPS16). For more information see www.start-project.de.
for an active pharmaceutical ingredient (API) to work as intended it must have a minimum level of stability, i.e., enough intact molecules have to reach the diseased cell before degrading into a variety of metabolites. In order to achieve this goal APIs are generally optimised for stability. This has two consequences: Firstly, APIs are not completely metabolised in the human body, but become excreted predominantly via urine and thus enter domestic sewage; secondly, the designed stability of the molecules widely prevents their biological degradation in today’s conventional sewage treatment plants (Ternes et al. 2004, 2005). Once emitted into rivers and lakes via the effluents of the plants the stable molecules find their way into ground water and, eventually, back to humans via drinking water.

Among the substances most frequently detected in water bodies across Europe are painkillers like diclofenac, antibiotics like roxithromycin, and antiepileptics like carbamazepine, antihypertensives like metoprolol, and X-ray contrast media like amiodotrizoic acid (Kümmerer 2008, SRU 2007). The measured concentrations range from a few nanograms to some micrograms per litre. Because of dilution, different natural degradation processes (biologically via microorganisms and photochemically via incident solar radiation), and adsorption onto suspended substances and soil particles, concentrations in rivers and lakes are typically higher than in ground waters.2 Aquifers can be particularly affected when they are close to contaminated surface waters. In Germany, more than one hundred different APIs have been detected in water bodies (Schulte-Oehlmann et al. 2007). Today there are no quality goals or threshold values for particular APIs in surface or ground waters, neither in Germany nor on the European level.

In Germany roughly two thirds of the drinking water is extracted from ground water. The rest comes from surface waters, bank filtration, or enriched ground water. Since concentrations of APIs in surface waters and bank filtrate are generally higher than in aquifers, drinking water from water works processing these two raw waters is generally at a higher risk of containing APIs. In Germany most of these water works therefore use activated carbon filtration (often combined with ozonation) for drinking water processing. With the exception of a few X-ray contrast media this has proven to be a powerful technique for eliminating APIs and other micro-contaminants (Püttmann et al. 2008, Ternes et al. 2005).

On the basis of the available data APIs have so far been rarely found in drinking water samples. In Germany 15 different substances have been detected so far (LANUV NRW 2007). At a few nanograms per litre, measured concentrations have usually been considerably lower than in surface or ground waters. Today neither the European Drinking Water Directive (98/83/EC) nor national regulations such as the German Directive on the Quality of Water for Human Consumption contain quality goals or threshold values for APIs.

Hazards for Human Health and Ecosystems

It is obvious, then, that the unintentional exposure of humans and wildlife to APIs takes place. But what is the nature, extent, and seriousness of these hazards? In terms of human toxicology pharmaceuticals belong to the best investigated chemical substances at all. As part of the market authorisation procedure an API is not only tested for its therapeutic efficacy but also for a multitude of unwanted side effects. An acute hazard for human health in the form of the occurrence of so-called adverse drug reactions as a result of consuming contaminated drinking water can be virtually excluded (Webb et al. 2003). It must be kept in mind however that testing for adverse drug reactions is generally not performed for particularly vulnerable groups like children and old people. The occurrence of unknown adverse effects even at the level of extremely small doses therefore cannot be ruled out at present on the basis of any sound scientific evidence. This holds true in particular for the chronic effects resulting from the life-long intake of APIs at trace levels, and the effects of mixtures of substances having the same mode of action (cocktail effects).

For basically the same reasons – lack of chronic effect data, unexplored cocktail effects, unknown toxicity of metabolites – the current state of knowledge about hazards to the fauna and flora due to APIs in waters is greatly limited. Most of the substances studied so far exhibit acute toxicity for aquatic organisms only at concentrations well above current values in surface waters (SRU 2007). Yet the example of 17α-ethinylestradiol (EE2) – the active ingredient of most hormonal contraceptives – shows that negative effects also occur at typical environmental concentrations: It has been shown that EE2, because of its high estrogenic potential, is one crucial factor contributing to the feminisation of male fish with habitats near the effluents of sewage treatment plants (Jobling et al. 1998). Generally, the current state of knowledge does not allow us to preclude that single animal or plant species might react particularly sensitively to a specific API at typical environmental concentrations – a claim supported by the case of the anti-inflammatory drug diclofenac which caused the near extinction of three of the most common vulture species in India and Pakistan (they had fed on dead cattle treated with the agent and subsequently died of renal failure) (Oaks et al. 2004).

Systemic Risks: Side Effects of Normal System Operation

Since there clearly is exposure, and there is also initial evidence for hazards, the notion of “risk” becomes relevant. By examining the figure we can see how the specific mechanism of risk production indicates the need for a systemic perspective. What becomes clear here is that it is the normal mode of operation of the healthcare system – namely the use of pharmaceuticals for treating and preventing diseases, and their intentional release into the water cycle – that may lead to a systematic, cumulative production of risks both for aquatic ecosystems and for the drinking water sup-

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2 Due to the purification properties of the soil layers not every substance occurring in surface waters infiltrates to aquifers. On the other hand human pharmaceuticals can enter ground waters directly via leakages in sewers, leaky landfill sites, and the use of sewage sludge in agriculture.
ply system. These risks, in turn, may eventually have, as a result of feedback through the water supply system, a blowback effect on health care itself.

This focus on the mode of risk production and the properties of the risk producer means abandoning classical risk analysis and adding a new component to the concept of systemic risks (cf. Renn and Keil, 2008, in this issue). It is not just events such as constructional faults, operating errors, malfunctions of system components, or disastrous external events that must be taken into account, but also the processes of self-endangerment brought about by modern, highly interconnected societies. For risk management this shift in analytical perspective has considerable consequences, because now strategies targeted at reorganising (parts of) the affected systems must be developed and implemented. Together with the particular structure of the risk knowledge this means that a risk governance (Renn 2008) approach to systemic risks in general and for pharmaceutical residues in drinking water in particular is needed.

Systemic Risks and the Precautionary Principle

Risk knowledge for the present case is highly uncertain, both with respect to the type and to the extent of hazards. In such a case of scientific uncertainty the precautionary principle (PP) as a legal instrument to deal with possible hazardous situations comes into play. Since the Maastricht Treaty (Treaty on the European Union, 92/C 191/01, article 174) the PP is one of the most important legal principles in European environmental legislation. It legitimises political decisions and the actions based on them, when “potentially dangerous effects” for humans and the environment have been identified but “scientific evaluation does not allow the risk to be determined with sufficient certainty” (Commission of the European Communities 2000, p. 4). Current European legislation, e.g., the obligatory accomplishment of an environmental risk assessment as part of the market authorisation procedure for a new pharmaceutical (Directive 93/39/EC), can be regarded as an outcome of the application of the precautionary principle.

In a stakeholder dialogue with experts from the pharmaceutical industry, water management, physicians and pharmacists associations, public health funds, and authorities, consensus has been reached that the PP should play a stronger role in dealing with API drinking water contamination. However, disagreement has arisen about the appropriateness of concrete precautionary measures given the existing uncertainties in assessing the risk. In the face of the ethical claim that environmental protection must not outweigh health protection this dispute highlights the “normative dimension” of the PP (von Schomberg 2006): Deliberating on precaution involves drawing on different sources of knowledge and interpreting this knowledge against a background of different interests, values, and needs. Deciding on measures is further complicated by the general “paradox of precaution” (Bechmann submitted): If a chosen measure is successful the risk at hand won’t materialise; consequently it is impossible to verify with hindsight if there would not have been a less intrusive, less costly solution to cope with the anticipated risk.

Approaching Systemic Risk Governance

An approach towards systemic risk governance starts from two assumptions. First, precautionary measures that aim at reducing the occurrence of APIs in waters should neither be detrimental to medical care nor should they inhibit pharmaceutical innovation. Second, precaution must be based on the principle of co-responsibility (von Schomberg et al., 2005). This assumes that many, if not most, risks modern societies face are caused by the interplay of a multitude of actors. Hence, the concept of individual role responsibility becomes increasingly inappropriate and a problem solution proves to be a task for many actors. Accepting co-responsibility requires providing actors with a clear idea of how they can contribute to precaution without compromising their own goals.

The main argument for such a participatory approach – and against a centralised solution by means of regulation alone – is the ethical claim mentioned above. For just about every API eventually the question has to be asked: “Can patients be deprived of an efficient drug for environmental reasons?” Obviously, in most cases the answer would be, “No!” (The case, of course, might be different if the efficacy of an API or its indication were highly questionable.) For this very reason, according to current legislation, authorisation of a new drug cannot be denied, even if ecological risks are doubtlessly assessed.

Systemic risk governance thus takes up the bottom line of the governance concept: a new form of organising collective action be-

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3 Already Perrow (1999), analysing high risk technologies, moved away from classical risk analysis by classifying risk systems on the basis of a characterisation of system properties. Perrow differentiates between “linear” and “complex” systems on the one hand and “tight” and “lose” couplings between system components on the other.
Drug Development

The primary aim of drug development is to achieve high efficacy along with as little adverse drug reactions as possible. One consequence of this is that the agent molecules are optimised for stability. Now this goal and rapid biological degradation in the environment are not necessarily in conflict, for whether a molecule is degraded slowly or rapidly does not depend solely on its structure. Indeed, it depends also, and crucially, on the conditions in the medium considered, such as frequency and intensity of light, pH-value, temperature, or type and number of microorganisms present. These conditions differ considerably in the human body and in the environment. In drug development such differences can thus be used if it is known which chemical moieties of molecules are particularly favourable to the application desired and which are particularly bad for rapid degradation in the environment. Given this knowledge it is basically possible to apply a new design principle: By means of targeted intervention in the molecular structure both the degradation of a “green” pharmaceutical in the environment and its functionality can be optimised (Kümmerer 2007).

For the pharmaceutical industry to take up this innovative approach two conditions would have to be fulfilled (Kümmerer and Schramm 2008): First, “green pharmaceuticals” indeed must not only have better environmental but also better — or at least similar — application properties, for only in this case would they gain competitive advantage. Second, successful examples of green drugs for different indication groups have to be available. Thus the long-term implementation of the new development principle requires inter alia setting up research programmes aimed at demonstrating its feasibility and economic efficiency via case studies. It is important to note that helping to enforce this new way of thinking in research and development not only contributes to solving the problems discussed here. As the approach is basically applicable to all chemicals its integration into education, research, and development could contribute to an overall increase in the level of sustainability in chemistry and pharmacy.

### Handling of Drugs

Precautionary measures can basically be applied in two ways: by decreasing drug consumption or by avoiding drug waste that may become disposed of incorrectly via domestic sewage (Deffner and Götz 2008). Motivating physicians to prescribe non-medicinal, generally constitutional forms of therapy is one contribution to decreasing drug consumption and to simultaneously strengthening preventive health care. Examples of such therapies are movement training, back training, or professional support in changing dietary habits. A prerequisite is that public health funds accept such a “recipe for a healthy living” by ensuring cost recovery. Swedish experience shows that such forms of prescription have a greater effect on patients than a simple medical recommendation. As empirical studies in start have shown this is also an effective way of meeting patient expectations concerning the “visible” result of a visit to a doctor.

Estimates assume that in Germany several thousand tons of pharmaceuticals end up annually as waste. A representative survey of the German population showed that, in 2006, a considerable portion of this to-

### Table 1: Precautionary measures for fostering the development of active pharmaceutical ingredients that are optimised both for efficacy in humans and for degradability in the environment. The highlighted measures were selected for the purpose of initiating a systemic risk governance process.

<table>
<thead>
<tr>
<th>DRUG DEVELOPMENT</th>
<th>RESEARCH AND DEVELOPMENT</th>
<th>ADJUSTMENT OF UNIVERSITY EDUCATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>research funding</td>
<td>Independent research institutions and medicinal product manufacturers are supported in the development of “green” active pharmaceutical ingredients.</td>
<td>Their set-up should promote rapid implementation of the new design principles in chemistry and pharmacy.</td>
</tr>
<tr>
<td>evaluation of the programmes</td>
<td>The focus of the evaluation will be the significance of a “green” product policy for the innovative capacity of medicinal product manufacturers.</td>
<td></td>
</tr>
<tr>
<td>examples of success</td>
<td>In order to promote a “green” product policy in the pharmaceutical industry a list of successful examples of “green” active ingredients will be published.</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CHANGE IN THE LEGAL FRAMEWORKS</th>
<th>COMMUNICATION MEASURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>extension of patent duration</td>
<td>awards and competitions</td>
</tr>
<tr>
<td>change of authorisation</td>
<td>These should promote “green” pharmaceuticals and sustainable pharmacy in research and education, as well as in the general public.</td>
</tr>
<tr>
<td>“Green” active ingredients become privileged through tightened coupling of the environmental risk assessment and the medicinal product authorisation.</td>
<td>public relations campaign</td>
</tr>
<tr>
<td>By running campaigns for sustainable pharmacy and the advantages of “green” drugs, their acceptance and marketability would be increased.</td>
<td></td>
</tr>
</tbody>
</table>

**COMMUNICATION MEASURES**

| awards and competitions | These should promote “green” pharmaceuticals and sustainable pharmacy in research and education, as well as in the general public. |
| public relations campaign | By running campaigns for sustainable pharmacy and the advantages of “green” drugs, their acceptance and marketability would be increased. |
tal was incorrectly disposed of via domestic sewage (Götz and Keil 2007). One reason for this behaviour is uncertainty about the correct way of disposal of unused or expired pharmacueticals – an uncertainty caused by inconsistent messages concerning disposal coming from the federal states and the municipalities as well as from waste management companies. The establishment of a consistent and binding disposal standard is necessary in order to effectively reduce improper disposal in the future. In the start project return via pharmacies has been recommended (Götz and Keil 2007).

**Technical Emissions Control in Urban Water Management**

The goal of sustainable emission management should be to remove problematic substances before they enter municipal sewage (Püttmann et al. 2008). A corresponding long-term strategy is the gradual implementation of sustainable sanitation concepts. These are based on the idea of separating the different waste water fractions at the location where they are generated, i.e., service water and toilet water are collected and treated separately. Since concentrations of APIs in undiluted toilet water are higher, available treatment techniques – like membrane bioreactors or fermentation methods – can, for physical reasons, be operated at significantly increased levels of efficacy. After being purified at the point of origin the different waste water fractions can either be discharged into the municipal sewer network or be directly reused. These concepts are of particular importance because they can be coupled with other sustainable techniques like energy recovery from fermentation processes in the faeces fraction of toilet water, or with the recycling of finite and already scarce resources like phosphorus from urine.

In any comprehensive survey of possible measures the use of advanced techniques in sewage treatment plants should also be included. However, none of the currently discussed techniques, such as activated carbon filtration, membrane filtration, or ozonation, is able alone to eliminate the whole spectrum of known APIs (Püttmann et al. 2008). Data from large scale pilot plants are needed in order to provide possible site-specific recommendations. As mentioned above the majority of water works using surface water or bank filtrate as raw water sources apply activated carbon filtration (sometimes together with ozonation). Since measures at the sewage treatment plants as well as the implementation of sustainable sanitation concepts would become effective only over a mid- to long-term perspective it should be examined whether individual water works need to upgrade accordingly in order to enhance drinking water protection (e.g., with respect to a quality goal of 0.1 micrograms per litre).

**Conclusions**

By assessing a set of different criteria like effectiveness, costs, and acceptance for the identified measures we concluded that a sustainable and comprehensive problem solution will not be possible if we only focus on one of the three spheres of activity (start 2008). The main argument is that even if all measures in one sphere were completely implemented neither every path of entry nor every substance could be captured in this way. This point is strengthened if questions of causation and responsibility are considered.

Formally the problem of the occurrence of APIs in drinking water originates from the health-care system. Following the polluter-pays principle one could argue that the latter should bear...
the costs of precaution. Correspondingly, urban water management would outright reject any strategy that mainly relied on the water works as a violation of that principle. Higher acceptance will only be achieved if right from the start the health-care system becomes involved in a comprehensive solution, bearing a part of the costs of precaution. The measures presented above have been designed in such a way that this effect can be achieved without imposing an unacceptable burden to a system already at its economic limits. If, simultaneously, the pharmaceutical industry takes steps to reduce the unwanted impact of their products in waters, a basis for a common policy may emerge.

The point of departure for such a participatory approach would be a set of measures whose implementation requires a relatively low effort and little or no cross-sector agreements (tables 1 to 3).

The idea here is that actually implementing these measures initiates a self-sustaining and self-enforcing process of building actor communities which are able to adopt further and more extensive precautionary measures. Decision makers at the municipal, regional, and national policy levels can initiate and sustain the process by designating API water contamination as a recognised societal problem and employing strategic communication programs to involve different actors. Experiences won during the start stakeholder dialogue sessions and the stimuli the project gave to actually implementing specific measures – such as joint initiatives of regional organisations, companies, and authorities to promote proper disposal of unused medication – have shown that there is at least some initial empirical evidence supporting the claim that a systemic risk governance approach to the problem of API water contamination has significant potential.

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References


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**TABLE 3:** Strengthening precaution by means of optimising wastewater disposal, wastewater treatment, and drinking water processing for the removal of pharmaceutical residues. The highlighted measures were selected for the purpose of initiating a systemic risk governance process.

<table>
<thead>
<tr>
<th>TECHNICAL EMISSIONS CONTROL IN URBAN WATER MANAGEMENT</th>
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<tr>
<td><strong>REDUCTION OF EMISSIONS OF ACTIVE INGREDIENTS INTO MUNICIPAL SEWAGE</strong></td>
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<tr>
<td>separation of sewage component flows</td>
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<td>hospital wastewaters</td>
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<tr>
<th>WASTEWATER TREATMENT IN SEWAGE TREATMENT PLANTS</th>
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<tr>
<td>assessment of advanced technologies</td>
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<td>increase of activated sludge age</td>
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<tr>
<th>DRINKING WATER PROCESSING IN WATER WORKS</th>
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<tr>
<td>activated carbon filtration</td>
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