Tailoring the precautionary principle to pharmaceuticals in the environment: accounting for experts' concerns

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Abstract

Over the past decade, scientists have detected an increasing number of pharmaceuticals in surface water and groundwater in urban areas. The effects of these pharmaceuticals on aquatic ecosystems are uncertain, although in some cases pharmaceuticals have been linked with effects such as the feminization of fish. As concern exists that pharmaceuticals in natural waters could have subtle, long-term effects on the reproduction, development, and/or behaviour of aquatic species, the precautionary principle could arguably be applied to induce management action to reduce the release of pharmaceuticals to aquatic environments. As part of a larger study on the management of pharmaceuticals in the environment, we interviewed 27 experts on pharmaceuticals in the environment from the academic, government, and industrial sectors, to ascertain their views on the precautionary principle, and its implications for pharmaceuticals in the environment. Most had a favourable opinion of the precautionary principle, but many also cautioned that it must be applied in a proportional and carefully balanced manner, and that it should include continued research. Based on the results of our interviews, we discuss how the precautionary principle can be tailored to the problem of pharmaceuticals in the environment, addressing the concerns of scientific and management experts, and reducing the levels of pharmaceuticals being discharge to aquatic environments.
Keywords: precautionary principle, pharmaceuticals, risk management, scientific experts, proportionality, adaptive planning, aquatic environment, uncertainty, surface water, interviews.

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1 Introduction

The precautionary principle (PP) is a decision making tool meant to guide society towards a sustainable future, by protecting human and environmental health. The best known definition is likely the one adopted from the Rio Declaration on Environment and Development: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." [1, Principle 15]. The precautionary principle is founded on several premises, including: 1) prevention of harm is preferable to attempting to undo damage once it has occurred, 2) lack of scientific certainty 3) reasonable scientific basis suggesting a potential for serious harm, 4) duty to act [2, 3]. Inherent in the precautionary principle is the concept that deciding to do nothing – to maintain the status quo – *is* a policy decision, and that a decision to do nothing should be considered and reviewed as carefully and as skeptically as a decision to mitigate risk [4].

The precautionary principle can arguably be applied to the problem of pharmaceuticals in the environment, a problem concerning which scientific understanding continues to emerge. Pharmaceuticals, or medications used to maintain human and animal health, have been detected at low (μg/L-ng/L) concentrations in surface water and groundwater in a number of countries, throughout the past decade [5-7]. This paper focuses particularly on human pharmaceuticals, which are often detected near urban areas, especially in developed countries, where relatively large quantities of pharmaceuticals are consumed. The main route through which human pharmaceuticals enter the environment is consumption, followed by excretion, sewage collection, and then treatment at a wastewater treatment plant. Improper disposal of unused pharmaceuticals can also lead to their entry into wastewater. Unfortunately, wastewater treatment plants are not designed for the removal of pharmaceuticals, and removal rates are therefore low, often near 60%, depending on the compound [7]. As a result, residual quantities of pharmaceuticals are discharged to surface water as part of treated wastewater effluent.

While it is becoming clear that pharmaceuticals are ubiquitous in aquatic environments, their effects on aquatic species and ecosystems remain uncertain. Many researchers believe that pharmaceuticals could have long-term, subtle, detrimental effects on aquatic organisms, due to their bioactive nature [8, 9]. 17α-ethinylestradiol, the active ingredient in the birth control pill, is believed to have contributed to fish feminization [10], and the anti-depressant fluoxetine has been found in laboratory studies to induce spawning in mussels [11]. However, most pharmaceuticals have not been tested on aquatic species, and for those which have demonstrated effects in laboratory tests, the question of whether or not similar effects would be seen at lower, natural concentrations, remains. Assessment of effects on organisms and ecosystems is further complicated by the possibility of additive or less than additive effects of mixtures of pharmaceuticals and other compounds [12, 13]. Traditional environmental risk assessments are generally ill-suited to pharmaceuticals, as they rely predominantly on acute tests,

whereas pharmaceuticals in the environment are only expected to have subtle, chronic effects [9].

In order to successfully integrate science into management, scientific experts are increasingly expected to work together with managers and to play a role in environmental decision making [14]. The purpose of our study was to assess the views and concerns of experts regarding the precautionary principle and its application to pharmaceuticals in the environment. Based on these, we discuss how the precautionary principle can be tailored to pharmaceuticals in the environment while meeting the needs of experts.

2 Research methods

As part of a larger study on the management of pharmaceuticals in the environment, 27 scientific experts from universities, governments of all levels, and industry, from Canada, the U.S., and Europe, were interviewed. The interviewees were mainly selected based on their contribution to the literature on pharmaceuticals in the environment and their participation in meetings and conferences on pharmaceuticals in the environment, although some were also chosen based on personal referral from other interviewees or contacts. Interviews were conducted in person whenever possible, with telephone interviews and e-mail questionnaires/interviews being used otherwise. Interviewees were asked two questions related directly to the precautionary principle, on which we report here: 1) Do you support the use of the precautionary principle in environmental decision making? Why or why not?, and 2) What do you think the precautionary principle means for pharmaceuticals in the environment?

3 Results

3.1 Concerns about the precautionary principle (Table 1)

In general, there was support for the precautionary principle among the experts interviewed, with 63% expressing a positive view of the principle, including 90% of European interviewees, 50% of Canadian interviewees, and 40% of interviewees from the U.S. However, several experts, including those who were in favor of the precautionary principle, expressed concerns about it. Their concerns mainly fell into 4 categories (Table 1):

1) Proportionality. The experts emphasized that precautionary action should be of a reasonable scale, proportional to the risk presented by pharmaceuticals in the environment (or other substances). Several experts stated that they felt the banning of pharmaceuticals because of environmental impacts was neither reasonable nor appropriate. The concern was raised that the precautionary principle had the potential to impede the development of technologies, such as pharmaceuticals, which might be beneficial to human health and well-being. A U.S. expert from the government sector believed the precautionary principle

Table 1: Examples of experts' concerns about the precautionary principle.

Proportionality of precautionary action	Definition	Socioeconomic balance	How much evidence is enough?	Other
"It doesn't mean you ban chemicals; it means you take an action, an appropriate action. Some people interpret the precautionary principle as in if there's any uncertainty, you ban it. And that's a very inappropriate response." – University, Canada	"The Rio Declaration, paragraph 15, is unintelligible and you cannot use it in public policy making." – University, Canada	" With limited resources, you have to reallocate some of them to these issues, and you take away from issues that are maybe more of an issue." – Government, Canada	"The question is, it's still a grey area around how much information is enough…what's the appropriate time to jump in?" – University, Canada	Adaptivity: "If such concerns can be reasonably ruled out, then restrictions should be loosened." – Industry, Europe
"What can you possibly do to somebody who needs to take a medicine?...Let's assume it does something to the environment, let's say if you think of a million people taking Advil all across the country, what possibly could Health Canada do that would solve the problem?" – Industry, Canada	"I think that the appropriate application of the precautionary principle with the intention of the preamble of CEPA (Canadian Environmental Protection Act) and Rio is very appropriate." – University, Canada	"No I do not [support the use of the precautionary principle]. Again, that's based on the use of public dollars." – Government, U.S.	"All the examples I read are times where with hindsight you should have used the precautionary principle. So I don't know at this stage, how serious it has to get, that you use it up front." – Government, Europe	Stakeholder participation: "All stakeholders have to be informed properly so that they can act properly." – University, Europe
"There's some people who say, you must not do anything because you don't know what the future holds…If the guy who invented immunization was around today, the precautionary principle wouldn't allow it to be developed. You don't know what immunization might do to people. But how many people's lives have been saved, and the quality of that?" – Industry, Europe	" The thing about the precautionary principle is that there are already diverging opinions about what it really means, how to use it." – Government, Europe	"My feeling is that all risks need to be balanced versus economic costs and other risks." – University, U.S.	"The real question is how robust is the scientific evidence on which to base judgement as to environmental risks/threats for various types of drug molecules." – Industry, Canada	Dialogue/Debate: "You need a dialogue, where people can actually have a debate, raise the questions." – Industry, Europe

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would require a goal of zero concentration to be set for pharmaceuticals in aquatic environments; the expert felt this was an unreasonable goal.
2) Definition. Several experts expressed concern about the lack of a clear definition for the precautionary principle. Perhaps not surprisingly, however, those who did discuss defining the precautionary principle did not agree on how it should be defined .The main concern regarding the definition was that a lack of definition would open the principle up to inappropriate use.
3) Socioeconomic Balance. The proper distribution of resources was of concern to several experts; financial concerns were the main reason cited by those who did not support the precautionary principle. Several interviewees emphasized that the risks of pharmaceuticals in the environment had to be balanced against other risks, including the risks incurred by taking precautionary action. There needed to be a prioritization of risks, as allocating funds to address the problem of pharmaceuticals in the environment would mean that the funds would not be available to address other problems. Several experts were concerned that the precautionary principle would not allow for such prioritization, and would lead to improper allocation of funds and unnecessary expenditures.
4) Sufficient scientific evidence to invoke the precautionary principle. A number of experts wondered about the level of scientific evidence required to invoke the precautionary principle. A European government expert pointed out that it is often only in hindsight that it becomes clear that management action should have been taken at a certain point; it is difficult to ascertain, as evidence of an environmental concern emerges, when the appropriate time is to engage in mitigative action

In addition to these four theme areas, individual interviewees raised several other concerns. A European industry expert who supported the precautionary principle made the case that it should be applied adaptively, with regulations and management strategies being adjusted to newly acquired information. A European university expert made the case that precautionary management needed to include disclosure of information to stakeholders, including the public, so that they could decide for themselves what sort of action to take. A second European industry expert emphasized the importance of societal debate concerning environmental problems, and expressed his concern that the precautionary principle did not allow for such debate.

3.2 Implications of the precautionary principle for the management of pharmaceuticals in the environment

Sixteen of the twenty-seven experts believed that applying the precautionary principle to pharmaceuticals in the environment required the implementation of management actions beyond research or risk assessment; however not all of them indicated which management strategies might be considered. Seven of the experts believed that the principle meant increased research into the problem of pharmaceuticals in the environment. Many researchers also felt that the precautionary principle meant pharmaceuticals should undergo environmental assessments, despite the current difficulties in applying traditional environmental assessment methods to pharmaceuticals. Environmental assessment regulations

for human pharmaceuticals exist in the US [15] and are under development in the EU and Canada [16, 17]. Those experts who did suggest specific management strategies as a result of applying the precautionary principle to human pharmaceuticals in the environment, favored, in particular, enhancement of sewage treatment technology; reduction of pharmaceutical over-use; development of 'green' (i.e. biodegradable, less toxic) pharmaceuticals; and environmental labeling of pharmaceuticals, although other management strategies were also suggested. Two experts listed negative implications, related to their concerns in Section 3.1: increased costs and difficulties in developing and marketing pharmaceuticals, and an artificial goal of zero concentration being set for pharmaceuticals in water.

4 Discussion

4.1 Defined or flexible precautionary principle?

While some experts were concerned that the lack of universal definition of the precautionary principle would lead to its being used inappropriately, we suggest that the flexible nature of the precautionary principle holds great potential, as it allows the Principle to be tailored to specific problems [18], such as the problem of human pharmaceuticals in the environment. Rather than resulting in its inappropriate use, the 'fuzzy' nature of the precautionary principle makes capable of being shaped by stakeholders, including scientific experts, so as to become most appropriate to a particular environmental problem. Thus the precautionary principle can be thought of as a source of both guidance and dialogue for environmental problems, rather than an artificially restrictive dictum.

4.2 Point of invocation of the precautionary principle

Among the main concerns of the expert interviewees was the question of the level of scientific evidence of harm required for the precautionary principle to be invoked. This question has also been the subject of discussion in the academic literature on the precautionary principle [19-21]. For example, Müller-Herold et al. [21] propose a scientific screening system for chemicals, through which the more persistent, bioaccumulative and toxic substances would be selected for precautionary management action, including banning. This approach is not well suited to pharmaceuticals in the environment, however, because pharmaceuticals are 'pseudo-persistent', being ubiquitous in aquatic environments due to constant release, rather than inherent persistence. Also, many of the subtle effects which pharmaceuticals may have on aquatic organisms are not linked to traditional toxicity or bioaccumulation [13, 22]. Furthermore, requiring a scientifically measurable and quantifiable basis for invoking the precautionary principle is somewhat paradoxical, as the precautionary principle is meant to address situations in which scientific measurements and quantification are lacking [18].

Perhaps these difficulties in defining a point at which the precautionary principle is invoked should suggest that a clear 'point of precautionary action' is illusory, and furthermore, unnecessary. As Rogers [19] points out , an as the comments of our experts imply, it is mainly the nature of the action resulting from application of the precautionary principle that leads to controversy. We suggest, therefore, that the discussion should focus on the nature of the *precautionary action* called for as the understanding of the problem of pharmaceuticals in the environment emerges, rather than on trying to identify a point at which the precautionary principle should be invoked.

4.3 Precautionary action: proportionality and balance

Proportionality of precautionary action to the risk presented by pharmaceuticals in the environment, and the balancing of the various costs of management action against benefits, were among the main concerns of the experts in our study. Proportionality is also one of the criteria emphasized by governments advocating the use of the precautionary principle; discussion papers on the precautionary principle produced by the European Commission and the Canadian Government both stress the need for proportionality of risk management based on the precautionary principle [23, 24]. What might proportionality mean for pharmaceuticals in the environment?

The concept of proportionality recognizes, as many of our experts underlined, that management action carries with it a cost, whether social, economic, or in the form of an increase in a different risk (or a combination of these). Therefore, precautionary actions with minimal costs – social, economic, and risk related – which at the same time meet the risk management goals, should be chosen. Risk management goals include a level of protection of the environment, but they may also incorporate elements which lead society broadly towards sustainability: for example, environmental stewardship, and environmental awareness. For human pharmaceuticals contaminating the environment, banning is not a proportional response. The costs in terms of human quality of life are too high, as there may be patients for whom only the medication in question can alleviate their symptoms. Instead, a more proportional and reasonable management strategy would be the labeling of the pharmaceutical as harmful to the environment, so that doctors can choose other medications when possible; or the listing of the medication as a last option drug. Pharmaceutical returns programs for unused medications could reduce the release of pharmaceuticals to the environment, while increasing consumers' awareness of the impacts they, as individuals, have on the environment. Having a goal of zero concentration for pharmaceuticals in the environment is neither proportional, nor is it achievable. In fact, the European Commission's discussion paper on the precautionary principle specifically states that zero concentration for environmental contaminants should not be a precautionary management goal [23]. Instead, an attempt should be made to reduce pharmaceutical concentrations in aquatic environments to being as low as *reasonably practical*.

Proportionality may also mean that upgrading *all* wastewater treatment plants to include enhanced treatment methods, such as ozonation or membrane

filtration, is not a good management option at this time. Firstly, this option would be extremely expensive [25], and would divert resources from other areas. Secondly, a European industry expert raised the point that upgrading wastewater treatment facilities would lead to greater energy use. Although water quality would be enhanced, the release of carbon dioxide to the atmosphere would be increased; both environmental compartments must be considered. Therefore, it may be more reasonable to target urban areas which release the greatest loads of pharmaceuticals to the environment, and areas where there is little dilution of wastewater, for enhanced wastewater treatment technology. Areas with other water quality problems resulting from the discharge of wastewater, which could be partly remediated by implementing enhanced treatment methods, should also be targeted. Monitoring of the quality of surface waters and wastewater treatment plant influents and effluents can be used to determine which areas are best suited for investments in enhanced wastewater treatment technology.

4.4 Precautionary action: adaptivity and research

Adaptive planning theory suggests that environmental management strategies should be flexible, account for uncertainty, and that the results of research and monitoring should be the basis for modification of management strategies [26, 27]. Ensuring that precautionary action adheres to the theory of adaptive planning may help to address the concerns of experts who emphasize the need for management action to be driven by continuing research. For pharmaceuticals in the environment, adaptivity may mean implementing management options such as pharmaceutical returns programs, pharmaceutical labeling, and education programs in the immediate future, while the effects of pharmaceuticals in the environment are still highly uncertain. These management strategies are easy to modify, if research indicates that environmental contamination by pharmaceuticals is either of greater or lesser concern than our current understanding suggests. If further evidence emerges that pharmaceuticals have detrimental effects on aquatic ecosystems, more permanent and more effective management options, such as advanced wastewater treatment technology, should be implemented in addition to existing strategies. Continuing research is essential to ensure that optimal precautionary management action is implemented.

4.5 Informing stakeholders and communicating risk

Several interviewees alluded to the importance of informing stakeholders such as the public about pharmaceuticals in the environment, and of having broad discussions of the issue. Informing and listening to stakeholders is an important component of the precautionary principle [28, 29], and the public should certainly be made aware of this environmental concern. Suggestions that the public need not be informed about the issue of pharmaceuticals in the environment due to the high degree of scientific uncertainty surrounding it [30] are misguided. Such secrecy will only increase mistrust of scientists and governments by the public [31, 32].

5 Conclusions

The experts we interviewed regarding the application of the precautionary principle to pharmaceuticals in the environment were generally supportive of the precautionary principle. Their main concerns were the degree of evidence required to invoke the precautionary principle; the need for precautionary action to be proportional to the risk presented by pharmaceuticals in the environment; accounting for all costs, financial and otherwise, of precautionary action; and the lack of a universal definition of the precautionary principle. The need for adaptive management, and for communication with stakeholders, was also highlighted. We suggest that the lack of definition of the precautionary principle is an advantage, allowing it to be tailored to specific situations like pharmaceuticals in the environment, and that rather than defining a specific point at which the precautionary principle is invoked, the discussion should focus on the types of precautionary action which suite the needs of scientific experts and managers.

References

[1] United Nations General Assembly, Report of the United Nations conference on environment and development. Rio de Janeiro. pp. 5, 1992.

[2] Quijano, R.F., Elements of the precautionary principle. Precaution, environmental science, and preventive public policy, ed. J.A. Tickner. Island Press: Washington. pp. 21-27, 2003.

[3] deFur, P.L. & Kaszuba, M., Implementing the precautionary principle. The Science of the Total Environment, **288**, pp.155-165, 2002.

[4] Santillo, D., Stringer, R. L., Johnston, P. A., & Tickner, J,. The precautionary principle: protecting against failures of scientific method and risk assessment. Marine Pollution Bulletin, **36(12)**, pp. 939-950, 1998.

[5] Heberer, T., Occurrence, fate, and removal of pharmaceutical residues in the aquatic environment: a review of recent research data. Toxicology Letters, **131**, pp. 5-17, 2002.

[6] Kolpin, D.W., Furlong, E. T., Meyer, M. T., Thurman, M. E., Zaugg, S. D., Barber, L. B., et al., Pharmaceuticals, hormones, and other organic wastewater contaminants in U.S. streams, 1999-2000: A national reconnaissance. Environmental Science and Technology, **36**, pp. 1202-1211, 2002.

[7] Ternes, T.A., Occurrence of drugs in German sewage treatment plants and rivers. Water Research, **32(11)**, pp. 3245-3260, 1998.

[8] Daughton, C.G. & Ternes, T.A., Pharmaceuticals and personal care products in the environment: Agents of subtle change? Environmental Health Perspectives, **107**, pp. 907-938, 1999.

[9] Sanderson, H., Johnson, D. J., Wilson, C. J., Brain, R. A., & Solomon, K, Probabilistic hazards assessment of environmentally occurring

pharmaceuticals toxicity to fish, daphnids and algae by ECOSARS screening. Toxicology Letters, **144(3)**, pp. 383-395, 2003.

[10] Jobling, S., Nolan, M., Tyler, C. R., Brightly, G., & Sumpter, J. P., Widespread sexual disruption in wild fish. Environmental Science and Technology, **32**, pp. 2498-2506, 1998.

[11] Fong, P.P., Zebra mussel spawning is induced in low concentrations of putative serotonin reuptake inhibitors. Biology Bulletin, **194**, pp. 143-149, 1998.

[12] Chen, C.-Y. & Lu, C.-L., An analysis of the combined effects of organic toxicants. The Science of the Total Environment, **289**, pp. 123-132, 2002.

[13] Daughton, C.G., Non-regulated water contaminants: emerging research. Environmental Impact Assessment Review, **24(7-8)**, pp. 711-732, 2004.

[14] Steel, B., List, P., Lach, D., & Shindler, B., The role of scientists in the environmental policy process: a case study from the American west. Environmental Science & Policy, **7**, pp. 1-13, 2004.

[15] FDA, Guidance for industry: Environmental Assessment of human drug and biologics applications. Government of the United States of America. 1998. Online, http://www.fda.gov/cder/guidance/index.htm

[16] CPMP, Discussion paper on environmental risk assessment of non-genetically modified organisms (non-GMO) containing medicinal products for human use. Committee for Proprietary Medicinal Products: London, UK., 2001.

[17] Health Canada, Health Canada to require environmental assessments of products regulated under the Food and Drug Act, 2002. Online, http://www.hc-sc.gc.ca/english/media/releases/2001.2001_98e.htm.

[18] Adams, M., The precautionary principle and the rhetoric behind it. Journal of Risk Research, **5(4)**, pp. 301-316, 2002.

[19] Rogers, M.D., Scientific and technological uncertainty, the precautionary principle, scenarios and risk management. Journal of Risk Research, **4(1)**, pp. 1-15, 2001.

[20] Sandin, P., Peterson, M., Hansson, S. O., Rudén, C., & Juthe, A., Five charges against the precautionary principle. Journal of Risk Research, **5(4)**, pp. 287-299, 2002.

[21] Müller-Herold, U., Morosini, M. & Schucht, O., Choosing chemicals for precautionary regulation: a filter series approach. Environmental Science & Technology, **39**, pp. 683-691, 2005.

[22] Sanderson, H., Johnson, D. J., Reitsma, T., Brain, R. A., Wilson, C. J., & Solomon, K. R., Ranking and prioritization of environmental risks of pharmaceuticals in surface waters. Regulatory Toxicology and Pharmacology, **39,** pp. 158-183, 2004.

[23] Commission of the European Communities, Communication from the Commission on the precautionary principle. Brussels, 2000. Online, http://europa.eu.int/comm/environment/docum/20001_en.htm.

[24] Government of Canada, A Canadian perspective on the precautionary approach/principle: discussion document, 2001. Online, http://www.ec.gc.ca/econom/discussion_e.htm

[25] Ternes, T.A., et al., Ozonation: a tool for removal of pharmaceuticals, contrast media and musk fragrances from wastewater? Water Research, **37,** pp. 1976-1982, 2003.
[26] Holling, C.S. (ed). Adaptive environmental assessment and management. International series on applied systems analysis. John Wiley & Sons, Chichester, 1978.
[27] Lessard, G., An adaptive approach to planning and decision-making. Landscape and Urban Planning, **40,** pp. 81-87, 1998.
[28] Jordan, A. & O' Riordan, T., The precautionary principle in contemporary environmental policy and politics, Protecting public health & the environment: implementing the precautionary principle, eds. C. Raffensperger and J.A. Tickner, Island Press: Washington, D.C. pp. 15-35, 1999.
[29] Gustavson, K.R., Applying the precautionary principle in environmental assessment: the case of reviews in British Columbia. Journal of Environmental Planning and Management, **46(3)**, pp. 365-379, 2003.
[30] Aumonier, J.R. Risk management of pharmaceuticals in the environment: the human pharmaceutical industry viewpoint, EnvirPharma, Lyon, France, 2003.
[31] Slovic, P., Perceived risk, trust, and democracy. Risk Analysis, **13(6)**, pp. 675-682, 1993.
[32] Hance, B.J., Chess, C. & Sandman, P.M., Setting a context for explaining risk. Risk Analysis, **9(1)**, pp. 113-117, 1989.