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December 2009

Swimming in Uncertainty

Addressing Organic Wastewater Contaminants in Iowa's Water

By William Wombacher

Anyone with internet access or a newspaper subscription has likely read recent headlines proclaiming the existence of pharmaceuticals in our drinking water. Headlines across Iowa, the Midwest, and the world have declared: "Investigation Finds Pharmaceuticals in Water;" "Medicines Found in Chicago Fish;" "Tests Find Traces of Drugs in Rock Island Water;" "Drugs Likely in Quad-City Water Supplies;" and "Traces of Cancer Drugs Found in UK's Tap Water."[1] While these reports shocked many in the general public, scientists have been aware of this problem for decades.[2]

More alarming and largely unpublicized in the popular media is the fact that pharmaceuticals pose only a very small portion of the problem. Thousands of other chemicals that humans use daily in their homes, on their person, and at their jobs are present in both rivers and lakes — and also in our drinking water.[3] These compounds, which are emerging environmental contaminants, are commonly referred to by scientists and researchers as Organic Wastewater Contaminants (OWCs) because they tend to resist treatment in traditional wastewater treatment plants.[4]

The most commonly detected OWCs in natural waters include synthetic fragrances used to scent soaps and lotions, Triclosan (anti-bacteria agents used in soaps), caffeine, fire retardants, and chemicals used in sunscreen and insect repellants.[5] Many people, in response to the presence of OWCs in our water, have suggested that improper disposal of pharmaceuticals is the main source of the problem and improved drug disposal programs are the solution.[6] Such programs would likely aid in reducing pharmaceutical concentrations in the environment and our drinking water. The problem, however, is that other compounds such as synthetic fragrances and Triclosan are in our water as a result of proper and frequent use, not from inappropriate disposal.[7] Thus, there is no simple or obvious solution to curbing the presence of most OWCs in our water.

OWCs remain in our water because of our failure to remove them during wastewater treatment.[8] Generally speaking, when a person washes clothes or hands, cleans the house and pours the water down the drain, takes a shower, or flushes the toilet, water and the chemicals are sent through a complex

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The Iowa Policy Project is a nonprofit, nonpartisan research organization that analyzes state policy issues. In particular we have looked at this topic before; in 2006 we released a report documenting the occurrence and persistence of emerging contaminants in an Iowa stream. Access this report at: http://www.iowapolicyproject.org/2006docs/060419-USGS-FullReport.pdf.

network of pipes to a wastewater treatment plant.[9] The main goal of a wastewater treatment plant is to clean the dirty water to a point where it can be reintroduced to a river or lake and not pollute the receiving body of water.

The majority of regulations regarding how clean this water must be are set under the Clean Water Act.[10] Wastewater treatment plants use these regulations to design treatment that will assure compliance with the law. However, no laws require the removal of OWCs. Without OWC water-quality standards, treatment processes are not designed to remove OWCs. Further, as currently built, many treatment plants would require major renovations to remove OWCs. As a result, these compounds are sent down our drains on a daily basis and persist through wastewater treatment processes.[11]

Typically, treated wastewater is discharged into a nearby lake or river, which means OWCs that have not been removed are released into the water ecosystem. Because humans constantly generate wastewater at their homes and workplaces, wastewater treatment plants are constantly operating and, as a result, continuously release OWCs into the environment.[12]

This problem is further compounded by the fact that many of our rivers and lakes are the source for water that we treat and use for drinking.[13] When a drinking water plant takes water from a river that receives wastewater discharges it is also taking in the OWCs that have persisted in the water.[14] While the drinking water treatment process is held to much higher standards than wastewater, many of these compounds are still not removed because they are not targeted during treatment.[15] The end result is the presence of OWCs in our drinking water.

This may not seem like a big deal because, after all, most of these compounds are present in products sold in grocery stores and are used on a daily basis. Common sense would suggest that if these compounds were actually harmful to us they would not be so easily accessible. The problem comes into focus, however, when we look at how we are exposed and what happens when we are constantly exposed to hundreds of these compounds. Not to mention that the safety of a chemical for human use does not always translate to safety for fish, animals and lower-level organisms.

While certain classes of OWCs must be tested before being sold, this is not true with all the others. The Food and Drug Administration, for example, requires significant testing for pharmaceuticals, including proof that the drug is safe for human consumption.[16] Compounds like synthetic fragrances, which are intended for cosmetic use and not ingestion, are subject to significantly lower standards.[17] Under FDA regulations, compounds such as synthetic fragrances and Triclosan must be safe for skin application, but those safety requirements do not consider that these compounds actually enter our bodies.[18] The fact is that OWCs are present in drinking water and while some may be tested and found safe for certain uses, there is no guarantee that the same is true when they are ingested or when they volatize into the air while we shower and enter our lungs.

The Risks of OWCs in Our Water

To analyze this problem we will use synthetic fragrances and Triclosan (the anti-bacterial compound in hand soap) as representative OWCs for the many that exist. While viewing this issue from the perspective of these two compounds will illuminate the challenges of the problem, it is important to note that they are two of the most well-researched OWCs and represent only a tiny portion of the compounds in existence. There are many other OWCs which have been subject to little or no research and there are others for which scientists have yet to develop tests.

The risks associated with OWCs in the environment occur in four forms: (1) inherent chemical specific risks of exposure, (2) the potential for bioaccumulation, (3) synergistic effects, and (4) the risks associated with our lack of knowledge.

Inherent Risks of Exposure

Synthetic fragrances were first detected in the environment in 1981.[19] Since then, scientists have discovered that some synthetic fragrances are carcinogenic and others negatively affect liver function in animals.[20] Synthetic fragrances have also been found to inhibit a process in mussels that helps it in rid itself of toxins.[21] Thus not only do synthetic fragrances have negative effects in and of themselves but can also reduce an organism's ability to protect itself from other compounds.

Triclosan has also been shown to negatively effect the environment. In fact, it has proved toxic to several species of algae.[22] While this may seem insignificant, algae is the basis of the food web and thus has the potential to affect many species that rely on delicate food chain interactions. Further, Triclosan has been proven to create significant quantities of chloroform, a probable carcinogen, when combined with chlorine.[23] This effect is of particular concern given that most drinking water is treated with chlorine in order to remove bacteria. Drinking water also contains chlorine when it comes out of your tap.

Risk of Bioaccumulation

In addition to inherent chemical specific exposure risks such as those described above, scientists are concerned that many OWCs are capable of bioaccumulating in humans and animals.[24] This refers to the ability of a chemical to accumulate in an organism's tissue over time.[25] This occurs because of continuous exposure coupled with an organism's inability to rid itself of the compound.[26] Even if an organism has the capacity to expel a certain chemical, if it is continuously exposed at a higher rate than it can process the chemical, it will accumulate. If fact, studies have found the presence of synthetic fragrances in human blood, milk, and tissue in addition to many species of fish and animals.[27] Thus, while the concentrations of OWCs in our water may be very low, they can stay with us beyond our initial exposure and increase in concentration in our bodies over time, increasing the likelihood of negative impacts.

Risks from Uncertainty

Another major concern is that there are hundreds and likely thousands of OWCs, with new compounds constantly being introduced as new products are developed, and scientists have very little information regarding the long-term effects of exposure.[28] One reason for this uncertainty is that testing for the chronic effects of very low-level exposures to even a single compound is extremely difficult and time consuming.[29] One paper suggests that "given the vast array of mechanisms of drug action and side effects, the total number of different toxicology tests possibly required to screen the effluent from a typical [sewage treatment works] could be impractically large."[30] While an array of sophisticated toxicology tests exists, the most traditional test typically involves exposing animals to high levels of a compound and then using the results to predict what will occur during longer term lower level exposures.[31] This data gets manipulated further when animal testing data is used to predict the effects of a chemical on humans.[32] The result is basically an educated guess, which leads to considerable uncertainty.[33] This uncertainty carries with it certain risks, such as how do we decide when an uncertain risk elevates to a level that warrants action.

Synergistic Effects

One final concern, closely related to the issue of uncertainty, is synergistic effects. This refers to the potential of OWCs to interact with other substances to create greater effects together than would occur individually.[34] This is a concern because we are rarely exposed to only one OWC at a time. [35] More likely, we will be exposed to dozens, if not hundreds, some of which may interact with each other to magnify effects or cause new unexpected impacts.[36] This issue is tied to uncertainty because scientists have trouble simply determining the individual effects of OWCs in the environment. Concern over the interaction of hundreds of compounds together adds an entirely new layer of uncertainty to the equation. This issue is closely tied to the notion of the precautionary principle, which is discussed later.

What is clear from this discussion is that scientists are generally aware of some low-level negative impacts associated individual OWCs in the environment and drinking water. The total scope of this problem, however, still appears to be out of reach. While this is a difficult problem, scientists and policy makers have not given up and are making significant progress in this field. Some of this research is being carried out in Iowa.

The Presence of OWCs in Iowa Water

Researchers at the University of Iowa are working on and have completed several studies measuring the presence of synthetic fragrances in the Iowa River, Iowa City drinking water, the soils of Cedar Rapids, the air above Lake Michigan, and Lake Erie and Lake Ontario sediments.[37] In 2006, a comprehensive study, conducted over the course of more than a year, examined the presence of synthetic fragrances in the Iowa River and the effectiveness of drinking water treatment at removing them.[38] During the study, water samples were collected at each stage of the drinking water treatment process; air samples were collected from the interior of the plant; and samples were taken of waste sludges produced during treatment.[39] All were tested for the presence of synthetic fragrance compounds.[40] The test results were then used to model the removal of the compounds during the treatment process.[41]

The study found that not only were synthetic fragrances in the Iowa River, but they were present in the drinking water leaving the University of Iowa Drinking Water Treatment Plant headed for consumption on campus.[42] The concentrations did decrease over the course of the treatment, but the synthetic fragrances were by no means completely removed.[43] Table 1, below, shows the removal efficiency measured in our study. AHTN and HHCB are abbreviations for two of the mostly commonly detected synthetic fragrances in natural waters. As Table 1 shows, these compounds were present at low levels, nanograms/liter, and were 67 percent to 89 percent removed during treatment.[44]

Table 1. Between 11 and 33 percent of two common synthetic fragrances remain in University of Iowa's treated drinking water[45]

	Average Concentration (ng/L)			
	Winter Samples		*Summer Samples*	
	AHTN	**HHCB**	**AHTN**	**HHCB**
Source Water	3.02	8.03	2.48	5.66
Drinking Water	0.62	2.39	0.26	1.86
% Removal	**79.3%**	**70.2%**	**89.3%**	**67.1%**

Our study found that the synthetic fragrances volatilized out of the water into the air and also attached to waste solids that were removed during treatment.[46] Thus, their partial removal was attributed not to targeted treatment but rather to the partitioning from water into other mediums as a result of compounds' chemical characteristics.[47] While the study only tested for synthetic fragrances, many OWCs behave chemically in the same manner as fragrances, so further testing would most certainly reveal the existence of many other OWCs.[48] Similar studies in other parts of the country have measured higher concentrations than those reported in the Iowa study, likely due to the fact that the University of Iowa Water Plant is not in immediate proximity to any wastewater discharges.[49] Because the University of Iowa plant is quite a distance downstream from any major discharges, OWCs have more time to interact with the environment, accumulate in soil and fish, and volatize into the air, which reduces their concentration in the water.

The Problem Illuminated

Scientists now know OWCs including fragrances, Triclosan and pharmaceuticals are present in the natural waters and drinking water of the United States and abroad.[50] They also know that plants and animals living in aquatic environments that receive wastewater discharges are being constantly exposed.[51] Further, humans are exposed to OWCs through their drinking water, volatilization of OWCs into the air from heated water, and also potentially from their food.[52] Scientists also know that some of these compounds are present at low levels and probably have negligible impacts on environmental and human health, however, many have not been adequately tested.[53] Further, while scientists do not know the exact risks posed by OWCs they are concerned about their widespread presence and their currently unquantified potential to cause harm.

This places policy makers in an unusual situation. Do we want to regulate a problem that we have uncertain information about, which will likely cost large sums of money? How do we decide when we have enough information to justify legislative action knowing it could be decades before the complexity of this issue it fully understood? Also, how can we regulate this problem in the face of so much uncertainty? These are extremely important questions that regulators must answer. Should we, and if so how do we, address the problem of OWCs in our water supply? As the following section will reveal, current U.S. toxic laws are inadequate to address the issue of OWCs suggesting that a new approach is necessary. Despite the shortcomings of federal law, however, the State of California and the European Union have adopted alternative approaches, which answer some of the questions posed above and show enormous potential to effectively address OWCs in the nation and Iowa.

The Inadequacy of Current U.S. Toxic Laws to Address OWCs

In the United States, toxic and hazardous substances are regulated by a number of statutes, which are designed to fit together to ensure that dangerous chemicals are monitored and regulated throughout their life cycle. For example, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) provide oversight during sale and production of chemicals, where the Resource Conservation and Recovery Act (RCRA) regulates the disposal of solid and hazardous waste. The Clean Water Act (CWA), on the other hand, regulates the presence of toxic chemicals in discharges to the nation's waters. While the system works well for many compounds, this patchwork of environmental laws also creates places where some chemicals can escape regulation.

There is growing concern by the public and scientific community about the presence of OWCs in drinking water and the natural waters of Iowa, however, under current environmental law there is almost no way these compounds can be regulated. As you will see below, the federal environmental statutes most applicable to this problem all contain provisions which make it nearly impossible to place restrictions on OWCs. Given the failure of current law to address this very real and very pressing environmental and human health issue, it is necessary to start rethinking how we regulate toxic and hazardous chemicals in the United States.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

This analysis will start with FIFRA and TSCA because both apply to the beginning of a chemical's life cycle. A discussion of FIFRA, which is the main statute regulating pesticides, may seem unusual given the emphasis on OWCs, however, Triclosan, the active ingredient in anti-bacterial soap, meets the definition of "pesticide" and is consequently regulated under that act.[54] FIFRA is a licensing statute, which means that it is used to control market access.[55] Only pesticides, which are registered under the statute, may be sold, used or distributed in the United States.[56] In order for a pesticide to be registered, the applicant must provide considerable information about the nature of the chemical including showing that it can perform its intended function, i.e. killing pests, without "unreasonable adverse effects to man or the environment."[57] Thus, a pesticide producer must prove that its product is reasonably safe in order for it to be sold. While this sounds like a great scheme, determining an "unreasonable effect" requires taking into account the "economic, social, and environmental costs and benefits of use."[58] Such considerations are what engineers and scientists refer to as a cost-benefit analysis.[59] Consequently, under FIFRA an "unreasonable effect" will only be found if the costs of not regulating a chemical outweigh the benefits of unrestricted use.

The use of a cost-benefit analysis makes regulation of OWCs unlikely. As previously mentioned, the biggest challenge for scientists on this issue is conclusively identifying the effects of OWCs. Thus for a compound such as Triclosan, which is of enormous benefit in preventing the spread of disease, the benefits of continued use may always outweigh the uncertain costs associated with its presence in the environment. It is also important to note that the cost-benefit analysis under FIFRA is done in a bubble.[60] It does not consider the potential effect of Triclosan when mixed with hundreds or thousands of other OWCs, which is one of scientists' main concerns.[61] While Triclosan seems like a sandbagged example given the enormous benefits society reaps from its use, the general uncertainty surrounding the negative effects of OWCs makes finding of an "unreasonable adverse effect" for any OWC with minimal societal benefit almost impossible.

The Toxic Substances Control Act (TSCA)

A similar problem occurs under TSCA, which is a gap-filling statute intended to regulate the sale and production of all chemicals not covered by other statutes.[62] TSCA, like FIFRA, is a licensing statute and also uses a cost-benefit analysis before restrictions can be imposed.[63] Further undercutting TSCA's effectiveness is that it only requires *existing* information on human health and environmental hazards be submitted as part of the registration process.[64] This creates a disincentive for chemical manufacturers to perform safety research, because if they find a danger they must submit it, but if they choose to be uninformed they need not submit any safety data. In fact, only about 15 percent of TSCA registration applications contain any health or safety data.[65]

More alarming is the process that the EPA must go through to require a producer to perform human health and environmental safety testing. The EPA must itself prove that there could be "unreasonable risk of injury to health or the environment" and then must perform a rulemaking using notice and comment procedures.[66] Only then will a chemical producer be required to perform additional testing. This process takes two to 10 years at an average cost to the EPA of $234,000 per rulemaking.[67] Only 200 chemicals have undergone this process since TSCA was passed in 1976 and only five chemicals or classes of chemicals have been subject to restrictive regulations under the statute.[68] To put this into perspective, the EPA receives approximately 1,500 TSCA applications each year and has reviewed more than 45,000 from 1979 to 2005.[69] Given the failure of this statute to explicitly require pre-registration safety evaluations and the fact that only five chemicals have received restrictive regulations, it is clear that emerging contaminants such as OWCs will not receive regulatory attention under its terms.

The Resource Conservation and Recovery Act (RCRA)

RCRA was created to serve as the primary statute addressing the safe disposal and handling of hazardous wastes.[70] Our discussion of this statute is minimal because RCRA exempts domestic wastewater, the single largest source of OWCs in the environment, from regulation.[71] Further, RCRA exempts any discharges permitted under the National Pollution Discharge Elimination System (NPDES).[72] The NPDES exemption suggests that the Clean Water Act, which created the NDPES program, is a better statute to regulate toxic pollutants discharged directly to the environment. Despite RCRA's deferment to CWA toxic provisions, however, these rules are out of date and incapable of adequately regulating toxic compounds.

The Clean Water Act (CWA)

Under the CWA, whose purpose is "maintain[ing] the ... integrity of the Nation's waters," there are two ways toxic chemicals are regulated: national effluent guidelines and state water-quality standards.[73] National effluent guidelines for toxic pollutants have been created for 65 compounds.[74] The problem is that not a single compound has been added to this list since the CWA was first signed into law in 1978.[75] In fact, since 1978 three compounds have been removed from the list.[76] Consequently, the list only addresses compounds with well-researched and established risks, unlike OWCs. The United States Government Accountability Office has acknowledged that the list was never intended to be final and that it does not include many of the most harmful toxic pollutants.[77] Even if the list were eventually amended, such amendments would likely only address well-established chemicals risks and not more controversial compounds such as OWCs. Because of the failure and unwillingness to update the toxic pollutant list, it is unlikely that the national effluent guidelines as presently written will ever be an effective means of regulating OWCs.

State water-quality standards are the second avenue available for the regulation of toxics under the CWA. Under the NPDES program, all those wishing to discharge pollutants into the nation's waters must apply for a permit, which specifies testing and treatment requirements.[78] All NPDES permits must also include effluent limits for pollutants that may be discharged at a level that causes or contributes to a violation of state water-quality standards.[79] This requirement gives states direct control over the quality of water within their borders. Many states, however, have failed to implement adequate water-quality standards or simply adopt limits for only the most dangerous chemicals, which results in only rudimentary control of toxic discharges.[80] Iowa, in line with many other states, has simply adopted EPA's suggested standards.[81] Iowa has not attempted to adopt more stringent standards for compounds such as OWCs.[82]

Because of the scientific uncertainty surrounding OWCs, the enormous but uncertain costs to remove these compounds, the likely strong opposition from the water treatment industry, challenge prospects for passage of Iowa water-quality standards for OWCs. Political pressure from diverse industry lobbies would be difficult to overcome and likely stress the use of a cost-benefit analysis, which would be problematic. Given our current scientific knowledge on the impacts of OWCs there is little, at present, Iowa can do under its CWA powers to affect the situation. Between the failure and unwillingness of the EPA to update the national toxic pollutant list and the lack of unified support for state water-quality standards, the Clean Water Act is ineffective for regulating OWCs.

As one can see from this analysis of federal toxic laws, the United States has no current statutory mechanism to effectively regulate OWCs. This is a result of the cloud of uncertainty that envelops the issue of OWCs and the fact that federal laws all require a high level of certainty before any regulatory action. In general a lack of information gathering requirements and the inability to regulate without certainty make the U.S. approach inadequate. Given the speed at which new chemicals are being introduced to the marketplace and, consequently, to the environment — more than 1,000 per year — there is need for a new regulatory regime.[83]

In order to effectively regulate OWCs, a new regime should seek to reduce uncertainty by requiring information gathering before market access is allowed. It should also acknowledge the need for regulation in the face of uncertainty, and place the cost of the externalities of toxic compounds on users and producers. While this paper paints a grim picture of the ability of current law to address OWCs, alternative toxic regulation schemes have been implemented in California and the European Union, which may be extremely valuable in attacking this problem.

Existing Approaches with Potential for Effective OWC Regulation

California Proposition 65

California is widely recognized for its laws on environmental safety. One example is the state's regulation of toxic chemicals. In 1986, California passed the controversial and revolutionary Safe Drinking Water and Toxic Enforcement Act (Proposition 65, or "Prop 65").[84] This statute places strict standards on the discharge of toxic chemicals into the environment and their presence in consumer products.[85] It is unique and independent of any federal regulatory regime.

The statute creates a regularly updated list of hundreds of compounds found to be carcinogenic or harmful to reproductive health and *bans* their discharge into any water that will ultimately be used as a drinking water source.[86] Unlike the toxic list in the Clean Water Act, Prop 65 requires that the list be reviewed yearly and allows additions to the list based on chemical toxicity studies occurring across the country.[87] Additionally the statute requires that businesses provide notice to the public prior to exposing them to a listed chemical; this includes their presence in consumer products.[88] The notice provision creates an enormous incentive for companies to reformulate products containing listed compounds because they otherwise must be accompanied by a label suggesting that the product is potentially carcinogenic or dangerous to reproductive health. The only way for a company to avoid these notices and discharge requirements is to show that exposure of the listed compound at 1,000 times the expected level poses no significant lifetime risk.[89] This requirement to prove safety at 1,000 times the expected exposure helps eliminate some of the uncertainty issues and builds a factor of safety into a typically inexact science. Additionally, it switches the burden from the EPA or another agency to prove the harmfulness of a chemical and requires the producer to instead prove that it is safe.

In addition to requiring the producers and users of dangerous chemicals to prove the safety of their products, Prop 65 also contains a citizen suit provision, which allows anyone to bring a lawsuit to enforce the statute, so long as it is in the public interest.[90] This practice takes pressure off the government for enforcement and also alleviates problems of enforcement priorities. Any citizen, including nonprofit organizations, can enforce these statutes based on their own agenda. There is no wading through bureaucracy to lobby government officials for enforcement; enforcement can happen as soon as a legitimate public concern exists. This reduces cost to the government for enforcement and also creates a market for enforcement actions. In fact, the Mateel Environmental Justice Foundation has been responsible for bringing lawsuits against hundreds of companies which have led to the reformulation of many products and the creation of warning labels.[91]

While Prop 65 has received the most attention for its impact on consumer products, it is important to realize that the reduction of hazardous compounds in consumer products also reduces their presence in the environment. When dangerous chemicals are phased out it translates to an elimination of a dangerous waste stream that previously would have been discharged into the environment. Thus, not only does Prop 65 have a direct impact on consumers it is also extremely effective at preventing environmental pollution.

Prop 65 is a far cry from the approach to toxics regulations taken by the Federal government. The statute is only a few pages long compared to the hundreds of pages of toxics statutes in the federal register.[92] Additionally, contrary to statutes such as TSCA, Prop 65 has been extremely effective. Hundreds of products have been reformulated to remove hazardous components.[93] Further, Prop 65 does what many federal statutes have attempted; it prevents harmful chemicals from entering our drinking water. Given Prop 65's ability, with relative simplicity, to address a problem that has eluded federal regulation for years, legislators should study it closely when considering effective means for regulating OWCs. Prop 65 addresses many of the shortcomings of federal toxic statutes and could be used as a model for the reformulation of our nation's toxic and hazardous chemical policies.

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Another alternative regulatory regime for toxic chemicals is the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation. Only recently enacted, in 2007, REACH contains a revolutionary strategy for regulating chemicals.[94] One of the most important aspects of this approach is that it explicitly incorporates the notion of the "precautionary principle."[95]

Under the precautionary principle, when information is incomplete, decisions should reflect a preference for avoiding unnecessary risk instead of avoiding economic expenditures.[96] The inclusion of this principle dispels the strict application of a cost benefit analysis and recognizes the need for regulation in the face of uncertainty, which is a necessary element to address OWCs. Like TSCA, REACH is a licensing statute which requires registration prior to sale.[97] Unlike TSCA, however, REACH requires significant safety testing before a compound can be sold in the EU.[98] While the requirements vary depending on the quantity of the chemical produced, almost all must include a safety assessment, an environmental hazard assessment, and a persistent, bioaccumulative and toxic assessment.[99]

Based on this information, the European Chemicals Agency (ECA) then decides whether restrictions are necessary because of an unacceptable risk to human health or the environment.[100] As part of this evaluation, the ECA considers the socio-economic impact of a restriction.[101] In other words, a cost-benefit analysis is required. While this requirement made the regulation of OWCs extremely difficult under FIFRA and TSCA, the initial information-gathering requirements make it less problematic under REACH. For example, the main reason the cost benefit is so detrimental under TSCA and FIFRA is that few or no requirements force a chemical manufacturer to analyze the human health and environmental impacts of its product. REACH, however, has substantial information-gathering requirements, which help alleviate some of the uncertainty.[102] While reliance on industry-performed testing offers a potential bias, detailed testing methods mandated under the EU regime should curb such an effect.[103] Under U.S. law the information-gathering requirements are so minimal that there is no chance for an even-handed cost-benefit analysis unless there happens to be toxicology information available from an independent source. REACH's information-gathering requirements, however, allow for a more fairly balanced cost-benefit analysis. Scientific uncertainty issues remain, but they are inherent in the nature of toxicology analysis, and not due to a lack of available information.

REACH's treatment of high-risk compounds is also unique. While all compounds must meet registration requirements, high-risk chemicals also require specific authorization prior to sale.[104] Authorization for high-risk chemicals comes only with proof that existing risk has been adequately controlled or where benefits of use outweigh the costs *and* there are no suitable alternatives.[105] The result is that even if a high-risk chemical can satisfy the cost-benefit analysis it still may be restricted if safer alternatives exist.

Another important aspect of REACH is that these regulations have a direct impact on the United States. Any U.S. company wishing to sell chemicals to the EU market must satisfy REACH requirements.[106] This will force many companies in the U.S. to comply with these new more restrictive laws. The importance is that this creates an excellent opportunity for U.S. policy makers to incorporate REACH requirements into U.S. law. Since many U.S. chemical manufacturers must comply with the new rules, it is likely that they would be supportive of domestic efforts to apply REACH restrictions on those companies operating only within the U.S. Alleviating some of the political pressure from big chemical companies would no doubt aid the passage of new chemical regulations. Additionally, as REACH matures, domestic policy makers can take note of the early success and failures when deciding how to apply its principles to the United States.

Elements Necessary for Successful OWC Regulation

Given the shortcomings of current U.S. toxics laws, the uncertain impacts of OWCs on our bodies and environment, and existing alternative approaches to toxic regulation, the following elements are essential to a new toxics regime capable of addressing OWCs and other emerging toxic problems.

- **Significant Information Gathering Requirements Prior to Market Access:** With 1,000 new chemicals being introduced each year, the only way we can stay on top of the effects of these compounds is to require substantial research prior to their manufacturer. Such requirements increase our knowledge base and allow policy makers to make more informed decisions. This information will also aid independent researchers in deciding what compounds may deserve extra attention.

- **Proof that a Compound is Safe for Humans and the Environment Prior to Market Access:** This incorporates the precautionary principle, which aids in regulating in the face of uncertainty. Instead of requiring a showing of certain harm to trigger regulation, the emphasis should be placed on requiring a showing of reasonable safety to allow market access. In this way, the costs of uncertainty will be borne by those wishing to profit from the sale of a compound rather than the citizens and organisms that are exposed to poorly researched and regulated chemicals.

- **Research Beyond Initial Registration:** As testing methods improve and research is expanded, there may be a need for reevaluation of currently registered chemicals. It is important that manufacturers are not completely relieved of their safety obligations after an initial bout of studies. This could be especially important as scientists come up with better ways to test the synergistic effects of OWCs.

- **Citizen Suit Provisions**: This will allow private citizens to aid in enforcement. Given the large number of OWCs and their varying impacts, the government will likely have to implement some sort of enforcement priorities to maximize enforcement efficiency. Citizen suits will allow private actors to aid in enforcement and do so independent of government agendas.

- **Public Notice Requirements**: One of the main reasons that Prop 65 is so successful is that companies fear the impact a warning label will have on their products' sales. While it is true that overuse of warning labels can lead consumers to simply ignore them, if notice was required for only certain harmful effects, such as reproductive health, it could eliminate the concerns about warning over-exposure and be extremely effective at encouraging product reformulation.

- **Retroactive Application**: Since thousands of chemicals have already fallen through the cracks under the current regulatory approach, the new regime must require chemical substances previously granted market access be reevaluated under the new requirements. Allowing chemicals to be grandfathered will simply perpetuate the lack of information and uncertainty that must be remedied for a new regime to succeed.

- **Nationwide Testing, Evaluation and Monitoring**: A comprehensive nationwide study of the presence of OWCs in the environment and drinking water is necessary to aid scientists and policy makers in further understanding the scope of this problem. While the United States Geological Survey has and is doing substantial research in this area, more resources are needed to undertake this massive task.[107] In 2008, the Water Assessment and Treatment Evaluation Research Study Act of 2008 was introduced to Congress in attempt to require the EPA to perform such research, however, the bill was extremely rudimentary, failed to provide a funding mechanism, and never made it out of the House Committee on Energy and Commerce.[108] In addition to a baseline study, there is need for ongoing testing to monitor changes and reevaluate risks. Given the scope and expense of such a testing and monitoring regime, a significant commitment from the states and the federal government will be necessary to effect this proposal.

Conclusion

The majority of U.S. toxic statutes passed in the 1970s at the very beginning of the environmental movement and, in the context of OWCs, have seen little substantive change. The knowledge and experience of policy makers and scientists at that time with regard to environmental issues pales in comparison to what they know today. Additionally, the economic and environmental climate today is significantly different. The methods embodied in our country's first crack at toxic regulation are inadequate for the current problems.

OWCs highlight this point. Currently, the rivers, lakes and drinking water of our country contain low levels of hundreds of compounds about which we know very little. In decades, when we finally have a better grasp of this problem, we may come to the realization that this no problem at all, or with a preponderance of ill effects to humans and our environment we may be forced to accept the exact opposite conclusion. The problem, as our laws currently stand, is there is very little we can do to curb this problem. We don't have enough information to regulate and we don't have enough scientists or funding to research the 1,000 new chemicals that are introduced every year. Without a substantial change in the way we approach toxic regulations this problem will be self-perpetuating.

Now is also a good time to address this problem given that many U.S. companies will have to meet REACH standards to do business in the EU. While there is no easy solution to this problem, there are several toxic approaches currently in force. Their strengths, weaknesses, successes and failures can guide a revolution in the way the U.S. address toxics. More than 30 years have passed since many of our statutes were passed. Since then our problems have changed, and so too must our approach to regulation.

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[1] *Investigation Finds Pharmaceuticals in Water*, CHICAGO TRIBUNE, April 20, 2009; Michael Hawthorne, *Medicines Found in Chicago Fish*, CHICAGO TRIBUNE, March 26, 2009; Tom Saul, *Tests Find Traces of Drugs in Rock Island Water*, QUAD-CITY TIMES, May 27, 2008; Tom Saul, *Drugs Likely in Quad-City Water Supplies*, QUAD-CITY TIMES, March 11, 2008; *Traces of Cancer Drugs Found in UK's Tap Water*, HINDUSTAN TIMES, Jan. 13, 2008.

[2] William Wombacher, *There's Cologne in the Water: The Inadequacy of U.S. Environmental Statutes to Address Emerging Environmental Contaminants*, COLO. J. INT'L ENVTL. L. & POL'Y at 1(forthcoming in 2010) (citing B. Halling-Sorensen et al., *Occurrence, Fate and Effects of Pharmaceutical Substances in the Environment – A Review*, 36 CHEMOSPHERE 357, 363 - 64 (1998)) [hereinafter *Cologne in the Water*].

[3] *Cologne in the Water*, *supra* note 2, at 2 (citing Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 36 ENVTL., SCI. TECH. 1202, 1204 (2002)).
[4] *See generally Id.*
[5] *Id.*
[6] *Id*. at 2. (citing Teirney Christenson, Note, *Fish on Morphine: Protecting Wisconsin's Natural Resources Through a Comprehensive Plan for Proper Disposal of Pharmaceuticals*, 2008 WIS. L. REV. 141, 162 (2008)).
[7] *Id*. at 3 (citing Ilene Sue Ruhoy & Christian G. Daughton, *Beyond the Medicine Cabinet: An Analysis of Where and Why Medications Accumulate*, 34 ENV'T INT'L 1157, 1166 (2008) (suggesting a significant portion of the pharmaceuticals detected in the environment can be traced to improper disposal of unused drugs, which can be remedied by stricter disposal regulations)).
[8] *Id*. (citing Jian-Jun Yang & Chris D. Metcalfe, *Fate of Synthetic Fragrance Musks in a Domestic Wastewater Treatment Plant and in an Agricultural Field Amended with Biosolids*, 363 SCI. OF THE TOTAL ENV'T 149, 155 (2006) and K. Bester, *Triclosan in a Sewage Treatment Process—Balances and Monitoring Data*, 37 WATER RES. 3891, 3893 (2003)).
[9] *Id*. (citing Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENVTL. HEALTH PERSPS. 907, Supplement, (1999)).
[10] IOWA ADMIN. CODE r. 667.62.3(1) (2009) (describing Iowa's effluent standards for biological oxygen demand, suspended solids, and other commonly targeted pollutants).
[11] *Cologne in the Water*, *supra* note 2, at 3 (citing Jian-Jun Yang & Chris D. Metcalfe, *Fate of Synthetic Fragrance Musks in a Domestic Wastewater Treatment Plant and in an Agricultural Field Amended with Biosolids*, 363 SCI. OF THE TOTAL ENV'T 149, 155 (2006) and K. Bester, *Triclosan in a Sewage Treatment Process—Balances and Monitoring Data*, 37 WATER RES. 3891, 3893 (2003)).
[12] Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENVTL. HEALTH PERSPS. 908, Supplement, (1999).
[13] The University of Iowa Drinking Water Treatment Plant, for example, uses the Iowa River as its main water source.
[14] William Wombacher & Keri H. Hornbuckle, *Synthetic Musk Fragrances in a Conventional Drinking Water Treatment Plant with Lime Softening*, 135 AM. SOC'Y OF CIVIL ENGINEERS J. OF ENVTL. ENGINEERING 1192 (2009) (showing the presence of synthetic fragrances in the raw water entering the University of Iowa Drinking Water Treatment Plant.).
[15] *Compare* Primary Drinking Water Standards under the Safe Drinking Water Act, available at: http://www.epa.gov/safewater/contaminants/index.html to IOWA ADMIN. CODE r. 667.62.3(1) (2009) (describing Iowa's effluent standards for biological oxygen demand, suspended solids, and other commonly targeted pollutants).
[16] Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 355 (2009).
[17] *Id*. at §§ 361-362 (2009) (showing the scant regulations for cosmetics and a lack of pre-market approval requirements).
[18] Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 361 (2009) (expressing the test for an adulterated comestic).
[19] *Cologne in the Water, supra* note 2, at 8 (citing T. Yamagishi et al., *Synthetic Musk Residues is Biota and Water from Tama River and Tokyo Bay (Japan).* 12 ARCHIVES OF ENVT'L. CONTAMINATION & TOXICOLOGY 83, 84 - 87 (1983)).
[20] *Id.* (citing Betty Bridges, *Fragrance: Emerging Health and Environmental Concerns*, 17 FLAVOUR AND FRAGRANCE JOURNAL 361, 368)
[21] *Id.* at 9 (citing Till Luckenbach, *Fatal Attraction: Synthetic Musk Fragrances Compromise Multixenobiotic Defense Systems in Mussels*, 58 MARINE ENVT'L. RES. 215 (2004)).
[22] *Id.* (citing Marie Capdevielle et al., *Consideration of Exposure and Species Sensitivity of Triclosan in the Freshwater Environment*, 4 INTEGRATED ENVT'L. ASSESSMENT & MGMT. 15, 16 (2008)).
[23] *Id*. at 9 (citing Krista L. Rule, *Formation of Chloroform and Chlorinated Organics by Free-Chlorine-Mediated Oxidation of Triclosan*, 39 ENVT'L. SCI. TECH. 3176, 3183 (2005); Report on Carcinogens, Eleventh Edition; U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program (describing the risk posed by Chloroform) available at: http://ntp.niehs.nih.gov/ntp/roc/toc11.html).
[24] *Cologne in the Water*, *supra* note 2, at 8 (citing Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENVTL. HEALTH PERSPS. 931, Supplement, (1999)).
[25] EPA.gov, Glossary, Abbreviations and Acronyms, http://www.epa.gov/OCEPAterms/bterms.html (defining bioaccumulants as "substances that increase in concentration in living organisms as they take in contaminated air, water, or food because the substances are very slowly metabolized or excreted.").
[26] *See* definition of "bioaccumulants", *supra* note 25.
[27] Wombacher and Hornbuckle, *supra* note 14, at 1192.
[28] *Cologne in the Water*, *supra* note 2, at 5 (citing Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 36 ENVTL., SCI. TECH. 1202, 1204 (2002) (listing 95 OWCs considered in that study)). *See also* Daughton, *supra* note 12, at 908 (discussing that little is known about the effects of pharmaceuticals in the environment despite the fact that those compounds are often some of the most well

researched); Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 36 ENVTL., SCI. TECH. 1202 (expressing the lack of scientific knowledge in this area).
[29] *Cologne in the Water, supra* note 2, at 11 (citing Ronald L. Meinick and John R. Bucher, *Science for Judges VII: Evaluating Evidence of Causation & Forensic Laboratories: Current Issues & Standards: Determining Disease Causality from Experimental Toxicology Studies*, 15 J.L. & POL'Y 113 (2007)).
[30] Daughton, *supra* note 12, at 923.
[31] *Cologne in the Water, supra* note 2, at 11 (citing Ronald L. Meinick and John R. Bucher, *Science for Judges VII: Evaluating Evidence of Causation & Forensic Laboratories: Current Issues & Standards: Determining Disease Causality from Experimental Toxicology Studies*, 15 J.L. & POL'Y 113 (2007)).
[32] *Id.*
[33] *Id.*
[34] *See* U.S. EPA Terms of Environment: Glossary, Abbreviations and Acronyms, http://www.epa.gov/OCEPAterms/sterms.html (last visited Oct. 15.2008) (defining synergism as "An interaction of two or more chemicals that results in an effect greater than the sum of their separate effects.").
[35] Daughton, *supra* note 12, at 924 (discussing synergistic effects).
[36] *Id*.
[37] Personal correspondence with Dr. Keri Hornbuckle, University of Iowa Department of Civil and Environmental Engineering Executive Officer. *See also* Peck, A.M., Linebaugh, E. and Hornbuckle, K.C. "Synthetic Musk Fragrances in Urban and Rural Air of North America." In Press. *Atmos. Environ. 40 (32) 2006, 6101-6111;* Peck, A.M. and Hornbuckle, K.C. "Synthetic Musk Fragrances in Lake Erie and Lake Ontario Sediment Cores." *Environ. Scie. Technol, 40(16), 2006, p 5629-5635.*
[38] *See generally,* Wombacher and Hornbuckle, *supra* note 14.
[39] *Id*. at 1193 - 4.
[40] *Id*.
[41] *Id.* at 1195 - 7.
[42] *Id.* at 1194 - 5.
[43] *Id.*
[44] *Id.* at 1195.
[45] *Id.*
[46] *Id.*
[47] *Id.* at 1196 – 7.
[48] Gerhard G. Rimkus, *Polycyclic Musk Fragrances in the Aquatic Environment*, 111 Toxicology Letters 37, 44 (1999) (discussing the potential for HHCB and AHTN, synthetic fragrances, to serve as bioindicators of wastewater).
[49] Wombacher and Hornbuckle, *supra* note 14, at 1193.
[50] *Cologne in the Water*, *supra* note 2, at 2 (citing Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 36 ENVTL., SCI. TECH. 1202, 1204 (2002)).
[51] Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENVTL. HEALTH PERSPS. 908, Supplement, (1999).
[52] *Id*. at 912-923 (discussing sources and origins).
[53] Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 36 ENVTL., SCI. TECH. 1202 (expressing the lack of scientific knowledge in this area).
[54] *Cologne in the Water*, *supra* note 2, at 15 (citing EPA.gov, Pesticide Product Information System (PPIS), http://www.epa.gov/opppmsd1/PPISdata/index.html (last visited Aug 30, 2009)).
[55] *Id*. at 16.
[56] *Id*. (citing 7 U.S.C. § 136a(a) (2008)).
[57] *Id*. (citing 7 U.S.C. §§ 136a(c)(5)(A-D) (2008)).
[58] *Id*. (citing 7 U.S.C. § 136a(c)(1)(F) (2008)).
[59] A cost benefit analysis is a decision making tool commonly used by policy maker ands engineers. Essentially it is a system whereby an action will not be pursued unless the benefits of that action outweigh the costs of the action. Typically this is applied on an economic scale.
[60] *See* 7 U.S.C. § 136(bb) (2008) (defining "unreasonable adverse effects on the environment" also stating that the costs of a pesticide will be weighed against the public health benefits specific to that pesticide suggesting that analysis is done in isolation).
[61] *Cologne in the Water, supra* note 2, at 10 (citing Christian G. Daughton & Thomas A. Ternes, *Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?*, 107 ENVTL. HEALTH PERSPS. 907, 924, Supplement, (1999)).

[62] John S. Applegate et. al., The Regulation of Toxic Substances and Hazardous Wastes, at 603 (Foundation Press 2000).
[63] *Cologne in the Water*, *supra* note 2, at 18.
[64] *Id*. (citing 15 U.S.C. § 2604(d) (2008)).
[65] United States Government Accountability Office, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS, GAO-07-825 at 8.
[66] *Cologne in the Water, supra* note 2, at 19 (citing 15 U.S.C. § 2603(a) (2008)).
[67] *Id*. at 20 (citing United States Government Accountability Office, CHEMICAL REGULATION: COMPARISON OF U.S. AND RECENTLY ENACTED EUROPEAN UNION APPROACHES TO PROTECT AGAINST THE RISKS OF TOXIC CHEMICALS, GAO-07-825 at 9-10.)
[68] *Id*. at 21. (Restrictive regulations have been passed under TSCA for polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium).
[69] *Id*. at 8.
[70] 42 U.S.C. § 6902(b) (2008) (discussing national policy for hazardous waste handling).
[71] *Cologne in the Water, supra* note 2, at 15 (citing generally Jian-Jun Yang & Chris D. Metcalfe, *Fate of Synthetic Fragrance Musks in a Domestic Wastewater Treatment Plant and in an Agricultural Field Amended with Biosolids*, 363 SCI. OF THE TOTAL ENV'T 149, 155 (2006)). *See also* 42 U.S.C. § 6903(27) (2008) (discussing the wastewater exception).
[72] 40 C.F.R. § 261.4(a)(2) (2008).
[73] 33 U.S.C. § 1251(a) (expressing the purpose of the CWA); *Cologne in Water, supra* note 2, at 22 (citing United States General Accounting Office, *Water Pollution: Stronger Efforts Needed by EPA to Control Toxic Water Pollution*, GAO/RCED-91-154 (2001) at 2).
[74] 40 C.F.R. § 401.15 (2008) (listing the 65 designated chemicals).
[75] *Cologne in the Water, supra* note 2, at 25 (citing EPA.gov, Toxic and Priority Pollutants, http://www.epa.gov/waterscience/methods/pollutants-background.htm (describing the establishment and subsequent modification of the toxic pollutant list)).
[76] *Id.*
[77] *Id.* (citing United States General Accounting Office, *Water Pollution: Stronger Efforts Needed by EPA to Control Toxic Water Pollution*, GAO/RCED-91-154 (2001) at 17).
[78] *See generally*, 33 U.S.C. § 1342 (2008).
[79] 40 C.F.R. § 122.44(d)(1) (i) (2008).
[80] *Cologne in the Water, supra* note 2, at 24 (citing United States General Accounting Office, *Water Pollution: Stronger Efforts Needed by EPA to Control Toxic Water Pollution*, GAO/RCED-91-154 at 30 (2001)).
[81] IOWA ADMIN. CODE. r. 567-61.3 (2009) (Table 1. Criteria for Chemical Constituents) (listing the water quality standards and suggesting that they reflect EPA suggestions).
[82] *Id*.
[83]*Cologne in the Water, supra* note 2, at 25 (citing United States General Accounting Office, *Water Pollution: Stronger Efforts Needed by EPA to Control Toxic Water Pollution*, GAO/RCED-91-154 at 2 (2001)).
[84] *Cologne in the Water*, *supra* 2, at 27 (citing Clifford Rechtschaffen & Patrick Williams, *The Continued Success of Proposition 65 in Reducing Toxic Exposures*, 35 ENVT'L. L. INSTITUTE 10850 (2005)).
[85] CAL. HEALTH & SAFETY CODE §§ 25249.5 - .13 (2008).
[86] *Id*. at § 25249.8.
[87] *Id.* at § 25249.8(b).
[88] *Id.* at § 25249.6.
[89] *Id.* at § 25249.10(c).
[90] *Id.* at § 25249.7(d).
[91] *Cologne in the Water*, *supra* note 2, at 29 (citing Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 367-8 (1996)).
[92] *Compare* CAL. HEALTH & SAFETY CODE §§ 25249.5 - .13 (2008) to 15 U.S.C. §§ 2602 – 2692; 7 U.S.C. §§ 136 – 136y; 42 U.S.C. §§ 6901 – 6992k; and 33 U.S.C. §§ 1251 - 1387.
[93] *Cologne in the Water*, *supra* note 2, at 28 (citing Clifford Rechtschaffen & Patrick Williams, *The Continued Success of Proposition 65 in Reducing Toxic Exposures*, 35 ENVT'L. L. INSTITUTE 10853 - 56 (2005)).
[94] *Id*. at 30 (citing European Commission: Environment Directorate General, *REACH in brief*, (Oct. 2007), available at: http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf).
[95] *Id.* (citing Regulation (EC) No. 1907/2006, concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), 2007 O.J. (L136) 3, Title I Art. 1 (1) and (3) [hereinafter "REACH"]).
[96] *See* EPA.gov, Glossary, Abbreviations and Acronyms, available at http://www.epa.gov/OCEPAterms/pterms.html (defining precautionary principle as "when information about potential risks is incomplete, basing decisions about the best ways to manage or reduce risks on a preference for avoiding unnecessary health risks instead of on unnecessary economic expenditures").

[97] *Cologne in the Water*, *supra* note 2, at 30 (citing American Petroleum Institute, *REACH: Registration, Evaluation, Authorization (and Restriction) of Chemicals: A Guide for API Members* at p. 5 (2008), www.api.org/ehs/health/upload/API_REACH_Guide.pdf (suggesting no registration means no global market)). *See also* REACH, *supra* note 95, at Title 2 Art. 7(1).
[98] *Compare* TSCA discussion *supra* pg 7 (requiring only the submission of existing data) with REACH, *supra* page 10, at Art. 14(3) (placing significant data submission and testing requirements prior to registration).
[99] REACH, *supra* note 95, at Art. 14(3).
[100] *Id.* at Art. 20(2) (describing the completeness check); Art. 41 (describing registration compliance check); and Art. (68)(1) (defining unacceptable risk to human health or the environment).
[101] *Id.* at Art. (68)(1).
[102] *Id.* at Art. 14(3).
[103] *See generally*, Council Regulation (EC) No. 440/2008 of 30 May 2008, 2008 O.J. (L.142) 1.
[104] REACH, *supra* note 95, at Art. 57 (describing compounds that are included as high risk). *See also id*. at Art. 56 (describing authorization requirements).
[105] *Id.* at Art. 60(2) (discussing the risk control) and Art. 60(4) (discussing the cost-benefit analysis).
[106] *Id*. at Art. 6(1) (Stating that importers are bound by the registration requirement).
[107] *See generally*, Dana W. Kolpin et al., *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, 36 ENVTL. SCI. TECH. 1202 (2002).
[108] Water Assessment and Treatment Evaluation Research Study Act of 2008, H.R. 6820, 110th Cong. (2008).