



Emerging Substances of Concern

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Division of Environmental Assessment and Restoration
Tallahassee, Florida***

December 2008

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Executive Summary

This report summarizes the conclusions of an internal Florida Department of Environmental Protection (DEP) Workgroup that was formed to evaluate strategies to effectively address a wide variety of potential contaminants, commonly referred to as Emerging Substances of Concern, or ESOC. These include global organic contaminants, such as flame retardants (PBDEs), pharmaceuticals and personal care products (PPCPs), endocrine-modulating chemicals (EMCs), nanoparticles, and biological metabolites. It is almost inevitable that small amounts of these compounds, which are manufactured to protect human health, improve consumer goods, or optimize agricultural production, are unintentionally released into the environment. Relatively recent improvements in laboratory analytical methods have enabled the identification of these substances, which likely have been present in waters for decades.

ESOC are particularly challenging for regulatory agencies because of their sheer numbers (there are approximately 14 million commercially available compounds in the United States) and because the majority of them (98%) are unregulated substances with a high degree of uncertainty associated with their environmental fate, transport, and toxicological effects. Because environmental risk cannot be meaningfully assessed for the vast majority of ESOC, traditional management practices, such as regulating specific analytes, must be modified to include other approaches, including prevention and effects-based environmental assessment methods.

After extensive discussion, the ESOC Workgroup identified several potential strategies for addressing ESOC, including the following:

- *Pollution prevention via stakeholder education;*
- *Assessment of ESOC data quality to better understand the magnitude of ESOC concentrations in the environment given the incorrect reporting of ESOC levels by some key researchers;*
- *Requests to the U.S. Environmental Protection Agency for specific ESOC monitoring projects; and*
- *Improved coordination with federal agencies.*

The ESOC workgroup believes that it is more efficient and effective for the EPA to proceed with a comprehensive, holistic national effort for addressing ESOC, rather than having individual states pursue a more limited, piecemeal approach. The Workgroup strongly agreed that it is imperative that a more effective “pre-release strategy” for ESOC also be implemented nationally by the federal agencies charged with regulating chemicals.

While this report describes all of the strategies, the Workgroup concluded that preventing ESOC from entering the environment is the most effective control strategy. Therefore, DEP’s initial efforts to address ESOC have focused on pollution prevention, including the development of a brochure by the Division of Waste Management on the proper disposal of unused pharmaceuticals, and the establishment of an ESOC “clearinghouse” website by the Center for Environmental and Human Toxicology, University of Florida.

1. Problem Statement

As of August 2007, more than 32 million substances were registered with the American Chemical Society's Chemical Abstract Service, with over 15 million of them being commercially available (Chemical Abstract Service website: <http://www.cas.org/cgi-bin/cas/regreport.pl>). Unfortunately, regulatory controls only exist for approximately 250,000 (1.6%) of these substances. Therefore, around 98% of the commercially available compounds are **NOT** inventoried and are essentially unregulated substances, some having a high degree of uncertainty associated with their environmental fate, transport, and toxicological effects. In less than two years (August 2005 to August 2007), more than 5 million new chemicals were added to the registry, and 5 million additional chemicals became commercially available.

At the current rate of chemical development, the fraction of unregulated to regulated chemicals will continue to increase exponentially. Once available in the marketplace, many of these substances are eventually released into the environment, where they pose an unknown level of risk to humans, animals, and plants. This creates significant challenges for DEP as a resource management agency, including the following:

- *Environmental monitoring and chemical-specific regulation for more than 14 million substances is impracticable due to the sheer number of compounds and potential cost of the monitoring; and*
- *There is a high degree of uncertainty associated with the environmental fate, transport, and toxicological effects of these substances due to:*
 - A lack of analytical methods that allow the confident determination of their presence.
 - A lack of toxicological studies that give direct information on how dangerous a substance is to various plant and animal groups.
 - The fact that environmental risk cannot be meaningfully assessed without such information, and, as a result, an effective agency action cannot be developed.

Recognizing these difficulties, DEP senior managers requested that a Workgroup be established to address Emerging Substances of Concern, or ESOC. A technical subgroup was formed and tasked with compiling and summarizing the existing knowledge of ESOC. This document briefly summarizes the information compiled by the subcommittee, and contains a variety of potential strategies for DEP senior managers to consider in dealing with this complex issue.

2. Background

This document uses the term “Emerging Substances of Concern” as a catchall term for this area of science. Within the scientific community, the term “Emerging Pollutants of Concern” has been modified several times to reflect the reality that not all of these substances are in fact pollutants. The term “Emerging Contaminants of Concern” is still frequently used, but the term “Emerging Substances of Concern,” or ESOC, is becoming more popular, as it recognizes that some of these substances are of natural origin and therefore should not be considered contaminants. The inclusion of the words “emerging” and “concern” are important because they reflect the current state of the science and policy.

The number of ESOC is not static, as the substances considered to be ESOC will change as the science evolves. New substances will be considered to be ESOC due to the inadequate characterization of their deleterious effects before they enter the marketplace, while “older” chemicals may no longer be considered ESOC because no adverse effects are associated with their occurrence in the environment. Still others will no longer be considered ESOC, not because they are not cause for concern, but because methods have been created for detecting their presence, fate, and effects, and standards can be created so they can be regulated like other, more common contaminants.

Although not widely recognized in the scientific literature, the term “microconstituents” has also been used to describe these substances. The use of the term “microconstituent,” rather than more descriptive terms such as contaminant, pollutant, or pathogen, is less likely to evoke a negative response. The public cannot tell whether a microconstituent is a good thing, such as an essential trace element, or a bad thing, such as a pollutant or pathogen. Therefore, the majority of the Workgroup agreed that the term “Emerging Substances of Concern” would be used to describe these materials.

For convenience, ESOC are categorized as follows:

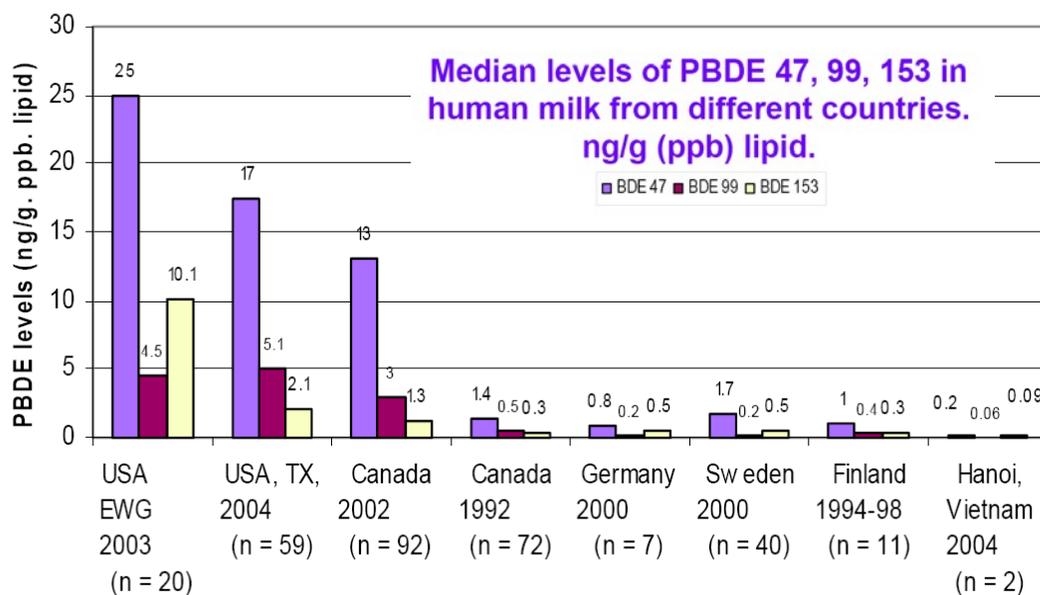
- *Global organic contaminants;*
- *Pharmaceuticals and personal care products;*
- *Endocrine-modulating compounds;*
- *Nanoparticles;*
- *Industrial chemicals (new and recently recognized); and*
- *Biological metabolites and toxins.*

It should be recognized that these categories are not exclusive and that many compounds fit into multiple categories. For example, a pharmaceutical product might also be an endocrine-modulating compound or contain nanoparticles.

Global Organic Contaminants include polybrominated diphenyl ethers (PBDEs), hexabromocyclododecanes (HBCDs), perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA), and siloxanes. PBDEs and HBCDs are flame-retardant chemicals that are applied to a

wide variety of everyday items such as clothing, upholstery, foam cushions, electronics, and automobile interiors. PBDEs do not chemically bind to the substrates to which they are applied, and so they are easily liberated. These moderately long-lived molecules are primarily released into the atmosphere, where they can be transported globally and readily bioaccumulate in biological tissues.

Recent research shows that PBDE tissue burdens are doubling in humans and animals every two to five years, with levels in human breast milk recently showing dramatic increases, especially in the United States and Canada (Birnbaum, 2006; Johnson-Restrepo *et al.*, 2005). PBDE concentrations as high as 419 nanograms per gram (ng/g) lipid weight have been reported in a sample of human breast milk from an Austin, Texas milk bank (Schechter *et al.*, 2003).



Source: Birnbaum, 2006.

Biomagnification factors for PBDEs ranged from 3:1 to 85:1 in sharks and dolphins in a Florida study (Johnson-Restrepo *et al.*, 2005). Chen *et al.* (2007) reported an extremely high concentration (40,900 ng/g lipid weight) of PBDEs in a common kestrel collected in Beijing, China.

PBDEs have been shown to have adverse effects (*e.g.*, interfering with reproduction and development) in mammals, birds, and invertebrates at “environmentally relevant exposures” (McKernan *et al.*, 2006, Wollenberger, 2005). In this sense, “environmentally relevant exposure” means that concentrations similar to those shown to have adverse effects in laboratory experiments have also been measured in the environment. Additionally, PBDEs have been shown to produce carcinogenic, endocrine-modulating, developmental, reproductive, and neurotoxicological effects (Birnbaum, 2005).

Pharmaceuticals and Personal Care Products (PPCPs) include all prescription and over-the-counter drugs, diagnostic agents, dietary supplements, fragrances, soaps, conditioners, sunscreens, cosmetics, caffeine, and nicotine. PPCPs also include antibiotics used prophylactically to prevent disease in livestock production (feedlot) operations. This diverse category of ESOC includes many water-soluble compounds. The most common mechanism for their entry into the environment is through wastewater discharges (municipal and septic drainage), land application of sewage sludge and manure, and landfill leachate. Depending on the type of treatment employed and the specific chemical(s) involved, wastewater or drinking water facilities may or may not be effective at removing these compounds from the effluent or drinking water. Receiving water concentrations of PPCPs typically range from nanograms per liter (ng/L) (parts per trillion) to low micrograms per liter ($\mu\text{g/L}$) (parts per billion), with caffeine and common pain relievers (e.g., ibuprofen) typically found in the highest concentrations.

Past laboratory studies suggested that environmental effects due to PPCPs were not likely at environmentally relevant concentrations; however, most of these studies were conducted with single compounds and did not account for interactions (additive, synergistic, or antagonistic) between ESOC, and may not have been of sufficient duration to capture adverse effects in the environment. More recent field studies suggest that estrogenic effects from PPCPs are occurring at observed environmental concentrations (Buxton, 2006; Schultz and Furlong, 2006; Kidd *et al.*, 2007). For example, a U.S. Geological Survey (USGS) study in Boulder Creek, Colorado, concluded that significant feminization of fish (skewed male-to-female ratios and an increase in individuals of indeterminate sex) was associated with the estrogenic effects of wastewater discharged from a wastewater treatment plant (Buxton, 2006; Schultz and Furlong, 2006). More research is needed on the fate and effects of PPCPs in complex effluents and their receiving waters.

Endocrine-Modulating Chemicals (EMCs) include natural and synthetic hormones, surfactants, pesticides, tributyltin, polychlorinated biphenyls (PCBs), and dioxins/furans. Estrogens are excreted by humans and are readily degradable under aerobic conditions, but they degrade slowly under anaerobic conditions. Conjugated estrogens, which are formed as the body eliminates estrogens, are not estrogenically active. However, these conjugated estrogens can be deconjugated in wastewater treatment systems, liberating active estrogenic compounds in the discharge.

A joint research project between Canadian and American scientists documented significant declines in a fathead minnow population in a lake dosed with only 5 to 6 parts per trillion of the synthetic birth control hormone 17 α -ethinylestradiol, when compared with an undosed control lake fathead minnow population (Kidd *et al.*, 2007). This concentration of ethinylestradiol has been reported in wastewater effluents in Canada and the United States. Potential effects from wastewater discharges could be even greater due to the additive or synergistic effects of other estrogenic compounds in the wastewater (e.g., natural estrogen, pesticides, surfactants, etc.) and should be studied.

Industrial EMCs include phthalates (plasticizers), nonylphenol and alkylphenol ethoxylates (surfactants, antifoaming agents, and plasticizers or ultraviolet stabilizers in plastics), bisphenol A (an ingredient in lacquers used to treat cans used for food goods), PCBs, dioxins/furans, PBDEs (flame retardants), and parabens (preservatives used in cosmetics and antibacterial toothpastes). Large-volume EMCs also include growth regulators widely used in livestock

production (feedlot) operations. Unmetabolized livestock growth regulators, along with prophylactic antibiotics (see **Pharmaceuticals and Personal Care Products**, above) are excreted in animal urine and manure.

A commonly used surfactant in the United States, nonylphenol ethoxylate, was recently banned in Europe due to its persistence, high bioaccumulation potential, and strong estrogenic effects (1/10,000 of Estrogen Equivalent, or EE). The EPA is in the process of recommending water quality criteria for nonylphenol ethoxylate (which may be as low as 1.4 µg/L in salt water) (EPA, 2003).

Besides being toxic at recommended application rates, many currently used or legacy pesticides—such as aldicarb, atrazine, chlordane, DDT, diazinon, lindane, mirex, parathion, permethrin, simazine, toxaphene, and tributyltin—may have endocrine-modulating effects on aquatic organisms (<http://website.lineone.net/%7Emwarhurst/pesticides.html>). These EMCs can alter neural input to the endocrine system; interfere with the hormonal modulation of the nervous system; and adversely affect the regulation of hormone and receptor biosynthesis, secretion, and metabolism. Exposure to EMCs has been shown to result in the feminization of fish, birds, and reptiles; the creation of feminized males in amphibians and fish; gynandromorphism in daphids; and abnormal development in fish and birds (Chapman, 2006).

Nanomaterials are natural and man-made structures, ranging in size from 1 nanometer (nm) to 100 nm, that are widely used in nanotherapeutic pharmaceuticals, drug delivery, cosmetics, personal care products, energy storage products, fabrics, lubricants, and even recreational equipment such as golf balls. Their use is already so ubiquitous that one would find it very difficult to avoid exposure to at least some form of nanomaterials. Due to their extremely small size, nanomaterials can pass through biological membranes and the blood/brain barrier. Additionally, nanomaterials display different physical and chemical properties than their parent compounds. For example, nonferrous metals such as gold or silver may become magnetized. Other nanoscale materials can act as catalysts or semiconductors. These properties only increase the likelihood that nanomaterials could produce unanticipated toxicological effects.

Christian Daughton, Chief of the EPA's Environmental Chemistry Branch, Las Vegas, explains the regulatory paradox associated with nanomaterials well:

“Regulatory conundrums result from the fact that although the constituent chemicals already might be regulated, the nanomaterial does not resemble or act like its constituents. This problem is exacerbated further by the fact that natural weathering processes could yet further alter these materials, producing ‘structurally undefinable ubiquitous xenobiotics’ (SUDUX), which may not be measurable for monitoring purposes” (Daughton, 2005).

Congress passed the 21st Century Nanotechnology Research and Development Act in December 2003, for the purpose of promoting the development of nanotechnology in the United States. However, the act did not contain any language related to the risks posed by nanomaterials, nor did it contain any language requiring additional assessment to determine their safety.

In February 2007, the EPA released a Nanotechnology White Paper (EPA, 2007), which included the following list of research needs:

- *Chemical and physical identification and characterization;*
- *Environmental fate;*
- *Environmental detection;*
- *Potential releases and human exposures;*
- *Human health effects assessment; and*
- *Ecological effects assessment.*

Research to date indicates that many of the nonorganic nanomaterials (ceramics, metals, and metal oxides) are inherently nonbiodegradable and are stable and persistent (EPA, 2007). They are also capable of bioaccumulating in the food chain (Biswas and Wu, 2005). A number of researchers have reported acute and chronic toxicity of various nanomaterials (Oberdörster, 2004a and 2004b; Lovern and Klaper, 2005; Lam *et al.*, 2004; Shvedova *et al.*, 2005; Fortner *et al.*, 2005). Some of the toxicity displayed by the nanomaterials could not be explained by parent material or particle size alone, indicating that other toxicological mechanisms maybe at work. As explained below, some nanomaterials possess many of the properties that would allow them to have a high propensity for adverse biological effects.

3. Assessing Environmental Risk

3.1 High-Risk Characteristics

Many millions of unregulated chemicals may be potentially associated with environmental risk, including items long thought to be benign, such as PPCPs. Improved analytical chemistry methods have resulted in the identification of many more chemicals in ambient waters or the tissues of organisms than were previously thought to occur. Considering the current information on ESOC, those with the highest propensity for adverse biological effects include those that are:

- *Persistent (structurally stable or consistent release);*
- *Bioaccumulative;*
- *Carcinogenic;*
- *Lipophilic;*
- *Acutely or chronic toxic;*
- *Endocrine disruptors, and/or*
- *Sized in the nanoscale range.*

Persistence may be caused by the structural stability of the chemical (e.g., a long half-life) or it may be a result of consistent loading to the environment. The latter is the case for many PPCPs, alkylphenols, and hormones/steroids that are consistently being released to the environment via wastewater effluents, landfill leachate, feedlot operations, or the land application of sewage sludges.

Persistent, lipophilic, bioaccumulative, endocrine-disrupting compounds that may also be carcinogenic—such as PBDEs and pesticides (and their associated breakdown products)—should therefore be the highest priority for regulatory control. As mentioned in the previous section, recent research suggests that some nanomaterials also possess many of these high-risk properties.

3.2 Challenges to Assessing ESOC Risk

The risk assessment process for ESOC is substantially more difficult than for common industrial compounds. Each step of the basic risk assessment process can be complicated by the potential paucity of data such as the following:

- *The analytical methods to detect and quantify the ESOC may not have been developed for each of the potential contaminants of concern;*
- *The potential exposure pathways may not be known if methods do not exist to identify and quantify the ESOC;*
- *Without the quantification methods, the potential dose cannot be determined, and;*
- *Without an estimate of dose, the risk cannot be determined.*

There are typically human health effects data for pharmaceuticals, although there may be few or no data for non-target exposures. Since the development of risk factors is generally limited to the substance's target audience (e.g., cholesterol medication is focused on the elderly), limited consideration is given to assessing the risk of unintended exposure to non-target groups (e.g., pregnant women or children). To apply the risk assessment process to ESOC, one must be willing to apply the appropriate uncertainty factors. However, the application of numerous uncertainty factors would have a compounding affect that would potentially render the risk assessment results useless. As such, it is highly likely that the classic risk assessment model simply will not work for ESOC.

However, once analytical methodologies and toxicological data are produced for these compounds, the level of uncertainty may be sufficiently reduced that an effective risk assessment could be performed. After an adequate level of certainty was achieved, the target pollutant would probably no longer be considered an ESOC. Rather, it would either become a regulated compound or deemed to be benign at environmentally relevant concentrations.

3.3 ESOC Data Quality

Based on requests from DEP's Springs Initiative, staff from DEP's Bureau of Assessment and Restoration Support conducted an on-site audit of the major national laboratory (USGS, Denver) that has produced much of the data concerning ESOC in Florida. Of great significance was the laboratory's practice of assigning numeric values to samples measured at concentrations below the Method Detection Limit (MDL), although the laboratory did qualify that the data were below the MDL. Since the MDL is the level at which there is 99% confidence that the actual concentration is greater than zero, values below the MDL most likely represent analytical noise. Thus, samples below the MDL should not be used to characterize the presence of an analyte in the environment. Some USGS investigators did not recognize the significance of the data

qualifiers (that the results were below the MDL), resulting in the misinterpretation of the data and the **overestimation** of the frequency of ESOC “hits” in Florida ground water and springs.

In a recent scientific journal article, Stackelberg *et al.* (2007) described the detection frequency for 106 ESOC in raw and finished drinking water from a large drinking water facility. The facility captured its source water from two streams that received more than 50 wastewater treatment plant discharges. The authors reported 100% detection frequency for caffeine in the source water; however, the laboratory’s reporting limit was 0.5 µg/L, and the highest detected concentration in the source water was 0.19 µg/L. This suggests that all the values should be considered as “estimated,” since the “detections” represented concentrations below known levels of precision and accuracy.

Other compounds were also reported as detected, despite their being quantified below the laboratory’s reporting limit. The authors then used summary statistics, such as the percent of the compounds tested that were detected in the raw and finished drinking water, to gauge the efficacy of the drinking water system in removing these compounds. The practice of using estimated values, some of which may represent analytical noise, to draw definitive conclusions, will only distort such evaluations and confuse the ESOC issue.

4. Current Regulatory Efforts To Manage ESOC

4.1 Pre- vs. Post-Release Regulatory Strategies

During Workgroup discussions, two fundamentally different strategies for the management of ESOC were identified. The first (pre-release) method involves subjecting each compound to a rigorous and comprehensive risk assessment process prior to approving the substance for commercial use. Substances with unacceptable risk would **NOT** be placed on the market. The ESOC Workgroup strongly supported a pre-release strategy as the most viable solution to the ESOC issue.

As an example of this type of strategy, the EPA has initiated the development of the ToxCast™ Program (<http://www.epa.gov/ncct/toxcast/news.html>) in an attempt to develop new methodologies for assessing the rapidly expanding number of environmental chemicals. The EPA hopes to develop the ability to “forecast” the toxicity of compounds based on their bioactivity and then to prioritize these chemicals for further screening and testing. The EPA would then use this information in the management and regulation of these chemicals.

The ToxCast™ Program is still in the planning stage. Several years’ worth of testing must be completed with chemicals of known bioactivity in order to develop the models that would be used to predict the toxicity of new chemicals. This first set of developmental testing is not scheduled to begin until at least 2009.

The second (post-release) strategy involves actions that regulatory entities would take **AFTER** the ESOC are found in the environment. The EPA has developed the following post-release strategy:

- *Engage in literature forensics (assess usage, environmental exposure and prevalence, persistence, bioaccumulation, and toxicity);*

- *Rank substances by risk based on the above considerations;*
- *Evaluate measurement methodologies;*
- *Carry out research to fill gaps in knowledge;*
- *Monitor the highest ranked candidates (for occurrence and ecological effects);
and*
- *Develop regulation and treatment technology as necessary.*

Although a post-release strategy will never be as effective as a pre-release strategy, the ESOC Workgroup concurs with this EPA post-release national strategy on ESOC. The Workgroup believes it will be more efficient and effective for the EPA to proceed with a comprehensive, holistic national effort, rather than having individual states pursue a more limited, piecemeal approach. However, the Workgroup strongly agreed that it is imperative that a more effective pre-release strategy for ESOC also be implemented nationally by the federal agencies charged with regulating chemicals (see discussion below).

4.2 Rethinking the Current Chemical-by-Chemical Regulatory Approach

Given the current rate of new chemical production, one must question the feasibility of a chemical-by-chemical regulatory approach. The EPA's ToxCast™ Program is a good first step toward dealing with the onslaught of new chemicals entering the marketplace, but additional testing and evaluation are needed to derive water quality criteria. Given that further chemical-specific criteria development by the EPA will be limited at best, the state of Florida will largely rely on narrative criteria (*i.e.*, "Substances in concentrations which injure, are chronically toxic to, or produce adverse physiological or behavioral responses in humans, plants, or animals – None shall be Present"; Subsection 62-302.530[62], Florida Administrative Code [F.A.C.]).

At this point it is probably unreasonable to expect that the EPA will be able to produce new water quality criteria for the flood of chemicals entering the market. How then should all of these new chemicals be managed? Since the use of a limited, chemical-specific target list for determining compliance has significant limitations, a new strategy is clearly warranted.

The EPA, through the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Drug Administration (FDA), through the Federal Food, Drug, and Cosmetics Act (FFDCA) and the Food Quality Protection Act (FQPA); and all federal agencies, through the National Environmental Policy Act (NEPA), are authorized to conduct pre-release risk assessments of all chemicals used in the United States. This strategy, if properly implemented, would prevent or limit high-risk chemicals from entering the marketplace, and ultimately, the environment. Unfortunately, there are simply too many ESOC for these federal agencies to address. For example, since TSCA was passed, the EPA (as of November 2005) has required fewer than 200 of over 62,000 chemicals to undergo additional testing. As of June 2005, the EPA has taken some form of action on only 3,500 of over 32,000 new chemicals submitted for review (11%).

The following text is excerpted from the FDA's website on the regulation of nanotechnology products (<http://www.fda.gov/nanotechnology/regulation.html>):

“Finally, FDA has only limited authority over some potentially high-risk products, e.g., cosmetics. As we noted earlier in this discussion, many products are regulated only if they cause adverse health-related events in use. To date there have been comparatively few resources available to assess the risks of these products. Other government agencies have different missions with regards to nanotechnology, e.g., to solve environmental problems, improve technology to address disease, etc. Few resources currently exist to assess the risks that would derive to the general population from the wide-scale deployment of nanotechnology products.”

As a result, millions of chemicals have entered the marketplace and the environment, without an adequate assessment of the risks they pose. Once a chemical enters the marketplace, much of the “burden of protection” shifts from the federal government to state and local governments. As a consequence, state or local resources must then be used for determining which chemicals should be removed from the marketplace, or otherwise controlled, and what should be done about those harmful chemicals that are already in the environment. This situation is not tenable in the long term.

The National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for preventing work-related injury, illness, and death. NIOSH, through the Nanotechnology Research Center, began assessing the hazards of various nanoparticles in 2004. To date, it has had to redirect funds internally each year in order to pursue research in this area. If NIOSH’s efforts are to be expanded, it would need direct funding for this program (U.S. Department of Health and Human Services [DHHS], 2007).

In contrast to U.S. policy, the European Union has adopted a new chemical regulation policy entitled “Registration, Evaluation, Authorisation and Restriction of Chemicals” (REACH), which went into effect on June 1, 2007. The REACH policy is based on the Precautionary Principle. The basic premise of this management philosophy is that no action is taken unless it can be proven that such an action is safe. It is similar to the “first do no harm” credo used in the field of health care. REACH requires companies that manufacture over 1,000 kilograms of a chemical to undergo a registration process and mandates the registration of 30,000 existing chemicals over the next 11 years. It shifts the burden of proof concerning a chemical’s adverse environmental effects from the government to the manufacturer, and also requires safer alternatives to be used, when possible.

4.3 State-Specific ESOC Initiatives (California Example)

The California Legislature asked the California Policy Research Center (a University of California program) to apply its extensive research expertise to the analysis, development, and implementation of state policy concerning ESOC (Wilson *et al.*, 2006). The request was prompted by the legislature’s interest in a California chemicals policy that would address public and environmental health concerns, while also building long-term capacity in the design, production, and use of chemicals that are safer for humans and the environment. Major findings included the following:

- *The scale of chemical production is immense and will continue to expand globally;*
- *There are extensive deficiencies in the federal regulation of chemicals:*

- Data gaps, safety gaps, and technology gaps.
- *Developments in the European Union (REACH) and among leading California businesses are driving interest in cleaner technologies, including green chemistry; and*
- *California needs a modern, comprehensive chemicals policy to address pressing public and environmental health problems and to position itself as a global leader in green chemistry innovation.*

Because many policy mechanisms could be employed to address the ESOC issues, Wilson *et al.* (2006) recommended that the California Legislature establish a chemicals policy task force to explore various mechanisms and develop a comprehensive policy.

5. Potential Strategies

After several meetings with extensive discussion, the Workgroup concluded that some ESOC, as by-products of human activities, may be present in the environment at low concentrations, where they may pose risks to human health and aquatic ecosystems. To avoid these potential risks until they are better understood, the ESOC Workgroup developed the following set of complimentary approaches to address ESOC:

- *Development of a “knowledge center” to support DEP staff and stakeholders;*
- *Community outreach and education on pollution prevention;*
- *Quality assurance activities focused on ESOC;*
- *Request for EPA assistance with Florida-specific research, monitoring, and pilot studies; and*
- *Improved coordination with federal agencies, including a request for national policy changes.*

The following describes each of these elements.

5.1 Pollution Prevention through Enhanced Public Information

ESOC Web-based Knowledge Center

Dr. Steve Roberts, Program Director of the Center for Environmental and Human Toxicology, University of Florida, led the effort to create an ESOC “clearinghouse” website that will eventually be hosted by DEP. A graduate student was hired to perform the technical work required to create the site, which includes links to technical information, EPA websites, and ESOC education information. Workgroup members collaborated in developing fact sheets for selected ESOC, including tungsten, estradiol, triclosan, perfluoro-octane sulfonate, and polybrominated diphenyl ethers. The website is available at:

<http://www.toxicology.ufl.edu/index.html>.

Community Outreach and Education

DEP's Division of Waste Management developed an informational brochure to inform Florida residents not to flush unused pharmaceuticals down the drain, due to the potential for environmental release through septic drainfields or wastewater treatment discharges. Additional information concerning pharmaceutical disposal guidelines was developed and provided to pharmacies statewide for them to share with their customers. The Division also has a web site on medications management at <http://www.dep.state.fl.us/waste/categories/medications/default.htm> that includes research papers, presentations and disposal guidelines. Staff receive many questions about medication disposal from residents, clinics, nursing homes, correctional facilities, veterinarians, hospices and other small generators. The Division is also making workshop presentations and providing technical assistance on pharmaceutical take-back events. Preventing ESOC from ever entering the environment is the most effective control strategy, as discussed in greater detail below. DEP should continue efforts to inform the public and stakeholders about the benefits of pollution prevention. Especially important to this effort will be partnering with industrial groups. A DEP fact sheet (which uses the term "microconstituents") is available at: <http://www.dep.state.fl.us/water/reuse/docs/MicroFact.pdf>.

Additionally, the Division of Waste Management has been working with the Product Stewardship Institute (PSI) to develop a national program for the "take-back" of pharmaceuticals. This program, which would potentially be funded by the drug manufacturers, would allow consumers to return their unwanted medicines to a pharmacy for proper management. The Division's PharmWaste listserv facilitates a dialogue for people working on this issue. With over 800 members worldwide, this listserv is used by PSI to communicate about their program. Other ways to prevent the environmental release of pharmaceuticals include product labeling to inform the public about proper disposal of unused products.

5.2 Quality Assurance Activities

Based on the audit findings mentioned earlier in the discussion, the ESOC Workgroup recommends that rigorous quality assurance activities be focused on the review of ESOC data. These substances are typically found in extremely low concentrations, often below analytical detection limits, and great care must be taken to properly interpret the data.

5.3 EPA Assistance with Florida-Specific Research, Monitoring, or Pilot Studies

The Workgroup recommends that DEP ask the EPA to consider ESOC projects that may provide data needed to stimulate the federal government to revise current national policies. The projects include the following:

- **Pesticide monitoring.** *Since many pesticides are substances of concern (e.g., may act as EMCs), the ESOC Workgroup suggested that the EPA provide funding for increased monitoring for these known pollutants.*
- **Response-based methods development.** *The EPA should develop an alternate strategy to assess potential harm to receiving water biota caused by ESOC, using effects-based or response-based methods. This may involve biomarker testing, measuring organism condition, using chronic toxicity*

methods, or assessing potential community shifts. If an effect is observed, efforts may then be directed to establishing the cause and, subsequently, towards mitigation.

- **Scoping studies.** *As an example of a scoping study, the EPA could analyze the tissue burdens, biomarkers, and population dynamics of fish inhabiting a potentially problematic wastewater treatment plant discharge for a variety of ESOC. Such an analysis would include a variety of bioaccumulative compounds to characterize the quantities of these substances in an area where they would be expected to occur.*
- **Fish tissue analyses.** *Since fish tissue samples are already collected as part of the statewide mercury Total Maximum Daily Load (TMDL) study, the Workgroup suggested that other ESOC also be analyzed as a cost-effective way to screen for their presence. Of particular interest are PBDEs (flame retardants), which were recently banned in Europe. DEP would provide these tissue samples to the EPA for additional analyses;*

5.4 Improved Coordination with Federal Agencies and Request for National Policy Changes

Members of the ESOC Workgroup believe that the most effective solution to the ESOC issue is to prevent substances with unacceptable environmental risk from being released into the environment in the first place. This can partially be achieved through an increased focus on public education (see **Section 5.1**), but the Workgroup also recommends that DEP formally request that its federal partners (e.g., EPA and FDA) improve coordination with the states on ESOC issues and adopt a new policy, similar to REACH, that would be the best step for ultimately resolving the ESOC issue.

Florida should also encourage federal action to improve chemical information, regulatory oversight, and support for green chemistry research, development, technical assistance, and education. Correcting the existing shortcomings in federal programs will require a contemporary, comprehensive approach, with the following goals:

- *To ensure that chemical producers generate, distribute, and communicate information on chemical toxicity, ecotoxicity, uses, and other key data;*
- *To strengthen government tools for identifying, prioritizing, and mitigating chemical hazards; and*
- *To support research, development, technical assistance, entrepreneurial activity, and education in green chemistry science and technology.*

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