

CONTAMINANTS OF EMERGING CONCERN PHARMACEUTICALS AND PERSONAL CARE PRODUCTS

*** PPCPs ***

PPCP is an acronym coined by the US EPA to define Pharmaceuticals and Personal Care Products. PPCPs are comprised of a wide variety of consumer products, including, but not limited to the following:

- Prescription and OTC drugs
- Veterinary drugs
- Vitamins
- Cosmetics and perfumes
- Sun screen products
- Skin lotions
- Shampoos and conditioners

*** PPCPs in the Environment ***

PPCPs enter the environment from everyone and everywhere, including:

- Medication residues pass through our bodies into sewer system
- External products are washed off our bodies into sewer system
- Unused or expired drugs are placed in trash

Although the human health effects of many of these consumer products are known within the context of their intended use, their impact on the environment to plants and animals is not so well known.

Contemporary debates center on the disposal of these consumer products in the environment and their potential detrimental impact on our drinking water and the plant and animal life on land or in the receiving streams.

PPCPs enter public sewer systems or onlot disposal systems everyday from our homes; or are tossed into the trash and end up in landfills. How many prescription drugs and OTC medications are in your own home?

Pharmaceuticals vary in how they are metabolized in a person's body. Did you know that approximately 10% of the ibuprofen you consume each day is excreted and ends up in the sewer system? One antiseizure medication is entirely excreted by the human body. Pharmaceuticals, of course, are more concentrated in the wastewater discharges from hospitals, long term care facilities and other medical facilities.

Since there are federal effluent limitations for the pharmaceutical manufacturing industry, discharges from manufacturing are more controlled.

*** Pharmaceutical Waste ***

How do you personally dispose of expired medications? Federal guidelines for *Proper Disposal of Prescription Drugs* from the Office of National Drug Control Policy are found on the internet at http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf and include the following recommendations:

- Take unused, unneeded or expired prescription drugs out of original containers and throw the drugs into the trash.
- Prescription drugs may be mixed with an undesirable substance such as coffee grounds or kitty litter or placing the drugs into empty cans or sealable bags before throwing into trash provides an added safeguard that the drugs will not be diverted elsewhere.
- Flush prescription drugs down the toilet ONLY if the label or drug information specifically states this disposal option. The FDA has a running list of drugs such as OxyContin and Percocet for which disposal down the toilet is recommended.
- Look into whether local or county governments or medical facilities in your community offer take-back programs.

About 5% of pharmaceuticals on the market are classified as hazardous. Therefore, these pharmaceuticals must be disposed of in accordance with hazardous waste regulations. Others are medical waste, and still others are nonhazardous wastes. Which category a discarded pharmaceutical falls into depends on its chemical, physical and toxicological properties as well as who generates the waste.

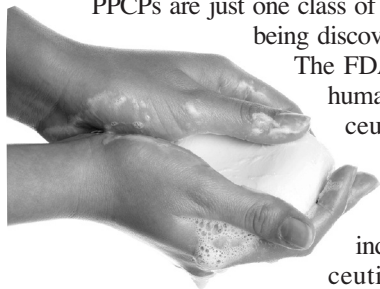


EPA proposed amendments to its Universal Waste Rule on December 12, 2008. The Universal Waste Rule, originally promulgated on May 11, 1995, modified the Resource Conservation and Recovery Act's (RCRA's) hazardous waste regulations by establishing a set of streamlined requirements for the collection of certain widely dispersed hazardous wastes, called "universal wastes." This proposed rule would facilitate better management of pharmaceutical wastes by streamlining the generator requirements and encouraging generators of hazardous pharmaceutical wastes to manage them under the provisions of the Universal Waste Rule, which ensures that these hazardous pharmaceutical wastes are properly disposed of and treated as hazardous wastes. In addition, this proposed rule would facilitate the implementation of pharmaceutical take-back programs by removing RCRA barriers in the collection of pharmaceutical wastes from health care and other such regulated facilities, as well as facilitate the collection of pharmaceutical wastes from households, including nonhazardous pharmaceutical wastes. As of this writing, the pharmaceutical waste amendments to the Universal Waste Rule have not been finalized.

* Pharmaceuticals Management *

Pharmaceutical management practices are still in their infancy stages at many locations across the country. Several organizations provide guidance to medical facilities on managing pharmaceutical waste. Two such organizations include Hospitals for a Healthy Environment (H2E) and the Product Stewardship Institute (PSI). The guidelines provided by such organizations hope to reduce health and environmental impacts from disposal of pharmaceutical wastes.

* Emerging Pollutants in Water *



PPCPs are just one class of emerging contaminants that are being discovered in our nation's waterways.

The FDA requires extensive testing on human health effects before pharmaceuticals and other personal care products are allowed to be placed on the market for use. Much of the recent test data indicate that the levels of pharmaceuticals, for instance, present in

drinking water or surface water are far below levels at which human health is affected. These trace levels are substantially below the level in a single pill.

However, even at very low levels that may not affect human health, some of these contaminants may have subtle effects on our aquatic environment, including impacts on development, spawning and other behaviors of aquatic organisms. This increased sensitivity of aquatic organisms is the reason POTWs are required to conduct Whole Effluent Toxicity Testing (WETT) on aquatic species. Most of the published aquatic toxicity data and risk assessments for pharmaceuticals are based on short-term acute studies and not long-term chronic studies.

* PPCP Testing *

The existing EPA Priority Pollutant list of 126 compounds found at Appendix A of 40 CFR §423 does not contain all of the organic compounds that make up PPCPs today.

Development of new test methods and more sophisticated laboratory testing equipment have contributed to the influx of new data on PPCPs and other contaminants in the environment. EPA released new methodologies in 2007 for pharmaceuticals, personal care products, and steroids and hormones. Such methods include EPA Method 1694 (74 pharmaceuticals and personal care products) and EPA Method 1698 (27 steroids and hormones). None of the aforementioned test methods are yet approved under 40 CFR §136. Therefore, it is prudent to note that there are also other test methods available that reliably measure the microconstituents in question.

Some pharmaceuticals are measured at less than 1 nanogram/L (ng/L), which is one-millionth of 1 mg/L. Other organic chemicals are measured at 1 picogram/L, which is 1,000 times lower than 1 ng/L. To reiterate, the PPCP concentrations being measured are very, very low.

Therefore, as our ability to test at lower and lower levels of pollutants is refined and more test data becomes available, public concern may increase. Chemical identification alone does not necessarily

indicate toxicity, especially when bioavailability, synergistic or antagonistic reactions, or the presence of undetected degradation products may alter the toxicity of the chemical itself.

An example of the ongoing PPCP testing is the latest Targeted National Sewage Sludge Survey Report released by EPA in January 2009 and found at <http://www.epa.gov/waterscience/biosolids/tncss-overview.html>. Metals, volatile organics, semi-volatile organics, flame retardants, pharmaceuticals, steroids and hormones were analyzed. Of the 72 pharmaceuticals tested, three were found in all 84 samples and nine were found in at least 80 of the samples. However, 15 pharmaceuticals were not found in any sample and 29 were found in fewer than three samples. EPA needs to conduct further evaluations to assess the significance of the presence of the PPCPs and other chemical compounds in the samples analyzed for this study.

* PPCP Treatment *

Municipal wastewater treatment plants are not necessarily designed to remove chemical compounds such as those that comprise the PPCPs. However, some PPCP compounds are removed through secondary treatment. One study conducted by the Water Environment Research Foundation (WERF) entitled, *Fate of Pharmaceuticals and Personal Care Products through Municipal Wastewater Treatment Processes*, evaluated the removal of aqueous phase (soluble) PPCPs as a function of solids retention time (SRT). It is determined that longer SRTs, also required for nutrient removal, are effective at removing many, though not all, PPCPs. The study also found that membrane bioreactors are less effective in the removal of PPCPs while reverse osmosis is very effective in removing the PPCP compounds tested. Other treatment processes evaluated in other studies that are found to be effective in PPCP removal from wastewater include ozonation, activated carbon and UV.

* Public Education *

Trace levels of PPCPs are viewed by the public as contaminants, no matter that the compounds are barely measurable and do not impact human health. So while a scientist may perceive PPCPs as a concern that needs to be investigated, the public may consider all the hype and news articles about PPCPs far more alarming.

The PPCPs issue could be significant for municipal wastewater treatment plant operators if regulations and subsequent standards are developed based on a public perception that a problem exists, even if the perceived environmental impacts are not supported by scientific evidence.

Therefore, one of our goals should be to educate the public. One tool of public education is to distribute the federal guidelines for *Proper Disposal of Prescription Drugs* mentioned on page 1 of this bulletin to your customers. POTW systems across the country have also developed public education programs, most of which are available on their websites. Search for "PPCP" on the internet and see what pops up!

One of the primary means of removing PPCPs from the environment is to reduce the compounds at the source – that means US!

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