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Good afternoon Madam Chairwoman and members of the Committee. I am Benjamin H. Grumbles, Assistant Administrator for Water at the United States Environmental Protection Agency (EPA). I appreciate the opportunity to describe EPA's comprehensive, four-pronged approach to pharmaceuticals and other contaminants of emerging concern in water and actions to evaluate the potential risks to human health and aquatic life posed by trace amounts of these contaminants in water, and to identify measures to minimize their occurrence. The Agency is committed to strengthening the science in evaluating the risks associated with such contaminants, improving public understanding and risk communication, identifying and increasing partnership and stewardship opportunities, and using appropriate regulatory tools.

EPA is concerned about contaminants of emerging concern in our water. EPA has been actively working with federal agencies and state and local government partners to better understand the implications of emerging contaminants such as pharmaceuticals and personal care products and endocrine disrupting chemicals detected in drinking water, wastewater, surface water and ground water. We continue to evaluate their occurrence, routes and levels of exposure, and potential effects on public health and aquatic life.

Over the last several years, EPA has increased its work in a number of areas to better understand contaminants of emerging concern, including pharmaceuticals and personal care products. We are focused on learning more about the occurrence of contaminants of emerging concern in water. In addition, we are working to better understand what treatment technologies may remove them from wastewater and drinking water. We are developing analytical methods to improve detection and quantitation capabilities. We are conducting national studies and field surveys to help direct our course of action. We are also partnering with government agencies, stakeholders, and the private sector, and increasing public awareness about product stewardship and pollution prevention.

We know collaborating with our partners will be critical so we can all make the best use of our existing resources and protect human health and the environment. Using technology and implementing regulations on a watershed basis, we place a strong emphasis on sound science, transparency, public information, and partnerships.

EPA's Four-Pronged Approach to Contaminants of Emerging Concern

EPA is responding to contaminants of emerging concern with a four-pronged approach aimed at strengthening science, improving public understanding, identifying partnership and stewardship opportunities, and preparing to take regulatory action when appropriate.

Strengthening the Science

Sound science and reliable information must be the foundation for any Agency decision. There is critical work to be done in the area of research and assessment before we can make any decisions as to whether regulatory actions are needed. EPA and other federal agencies are working on projects to evaluate exposure and potential effects on humans and aquatic life. This is key because, while we know that pharmaceuticals have health effects at the therapeutic dose, but we do not know if there are effects associated with long-term exposure at much lower concentrations of the same chemicals. Effects may be more likely in aquatic life because they are continually exposed.

Several EPA offices, including my Office and the Office of Research and Development, are working together to better understand potential issues related to exposure pathways and health effects of contaminants of emerging concern. For example, a key area of research is assessing the sources of contaminants of emerging concern in water. Important to this effort is having available and reliable analytical methods so we can detect and quantify these contaminants with confidence. In December 2007, the Agency released newly developed, cutting-edge methods for the analysis of approximately 100

pharmaceuticals, personal care products, steroids, and hormones in raw sewage, treated wastewater, and biosolids which are some of the most complex samples to test. In addition to these new methods, EPA has validated a new pesticide detection method in a single laboratory, but other labs have not yet confirmed this result, and revised the existing flame retardants (polybrominated diphenyl ethers or PBDEs) method to more accurately detect these contaminants in wastewater samples. The availability of the methods responds to requests for guidance in this area and supports studies being conducted by the Agency. We will continue to consider and evaluate additional methods.

EPA, other federal agencies, and academic and private sector researchers are studying the occurrence of contaminants of emerging concern in wastewater, surface water, ground water and drinking water, as well as in fish and other aquatic life. EPA's Office of Water is taking several actions, including:

- A study at nine publicly owned wastewater treatment facilities (POTWs) to better understand what is going into the plant for treatment and what is coming out in the discharge. We expect to have a preliminary report by December 2008.
- A pilot study to investigate whether pharmaceuticals and other personal care products may occur in fish from five effluent-dominated streams across the US. The study results are undergoing quality assurance review.
- A Targeted National Sewage Sludge Survey of biosolids from 74 randomly selected wastewater treatment plants to determine whether contaminants occur in biosolids, and if so, at what concentration. We expect to complete this study later this fall.

- Grants to University of Florida and Duke University funded by EPA to assess occurrence of contaminants of emerging concern in wastewater and biosolids. Researchers are studying the occurrence, fate and transport, and treatability of contaminants of emerging concern like triclocarban (an antiseptic widely used in soaps and other products) and steroids and hormones in biosolids and wastewater. Duke University is in the process of evaluating the results of its study at four POTWs. The University of Florida grant to evaluate biosolids was recently extended until 2010 to conduct additional work.

In addition to these studies, we recently announced a number of new efforts that the Office of Water is undertaking:

- Building on the fish tissue pilot study, the National Rivers and Streams Assessment will monitor fish tissue and water samples at 154 developed/urban sites to develop statistically representative estimate of the occurrence of pharmaceuticals and personal care products is in fish tissue and waterways in developed/urban areas across the country. The results should be publicly available in 2011.
- EPA is working to better understand and evaluate the potential risk to humans of low concentrations of contaminants of emerging concern in drinking water. EPA has commissioned the National Research Council of the National Academy of Sciences to convene a panel of experts to provide their individual ideas and opinions on this subject. The panel will meet in December 2008.

EPA's research agenda also includes a broad range of work to better understand contaminants of emerging concern in water in the following areas: sources, fate and transport, exposure pathways (human and ecological), human health and ecological assessment and risk management. Research supported by EPA's Office of Research and Development is increasing our understanding of possible exposure routes and effects contaminants of emerging concern may have on humans and aquatic life.

Another important research area is treatment and removal of pharmaceuticals from wastewater and drinking water. While EPA is active in this area, research foundations representing drinking water and wastewater utilities are key players in evaluating the removal efficiency of different types of treatment. Research is finding that higher-level treatment strategies are more effective at removing certain types of contaminants of emerging concern, including pharmaceuticals.

Improving Public Understanding

One of the most difficult tasks faced by public health and environmental officials is how to communicate risks in the face of uncertainty. Useful information should be shared with the public in a timely way as it is generated. It is important to communicate with the public so that they can help shape effective public policy in this area and make informed choices. We recently created a new publicly accessible web page (www.epa.gov/waterscience/ppcp/) to provide information on the work that we are doing on contaminants of emerging concern in water, in particular, pharmaceuticals and

personal care products. In addition, EPA has a website that details all of the research the Agency is conducting or funding on pharmaceuticals (www.epa.gov/ppcp/).

We will continue to work with all of our stakeholders to communicate available data on both occurrence and health effects for contaminants of emerging concern, and any associated uncertainty with those data. It is essential for us to share information and understand stakeholder concerns so that we can work together as effectively as possible in communicating with the public.

Identifying Partnership and Stewardship Opportunities

To be successful, we must work with other federal, state, and local agencies and industry to assess the occurrence and effects of contaminants of emerging concern, analyze their risks, and take appropriate actions to reduce those risks.

For example, EPA worked with the White House Office of National Drug Control Policy last year to develop federal guidelines that recommend appropriate disposal methods for unused medication. While most pharmaceuticals from human sources are entering water through natural biological functions, it is also important the public understand the toilet is not a trash can for most unused medications.

EPA has also been working to develop and promote good stewardship efforts such as take-back programs that would allow consumers to properly dispose of unwanted or

unused pharmaceuticals. Take-back programs and events are collection methods that reduce the quantity of unused pharmaceuticals entering the environment and reduce the amount of drugs available for diversion, theft, or accidental poisoning. EPA recognizes that these programs must be consistent with the Controlled Substances Act and regulations for managing medications that are also classified as controlled substances. The Agency will work with DEA to ensure that pilot take-back programs supported by EPA are conducted safely and in compliance with federal and state laws and regulations.

Along these lines, EPA recently funded a grant to the Area Resources for Community and Human Services in St. Louis. Last year, the Aging Initiative in EPA's Office of Children's Health Protection and Environmental Education provided a grant to this community partnership, which is piloting an efficient regional model to responsibly dispose of unwanted, non-controlled medications using a regional grocery store chain as the collection point. The grantee is evaluating this pilot take-back program for its potential broader applicability.

In addition, EPA's regional offices have sponsored or provided grants to local communities to support several activities related to the prudent disposal of unused medications, including the successful April 2008 "Great Lakes Earth Day Challenge," which collected nearly 4.5 million pills for safe disposal.

As part of EPA's broader strategy to strengthen and expand technical partnerships and information sharing at all levels, we asked the states to share information with us on take-

back programs, and current or planned monitoring programs for pharmaceuticals and personal care products in wastewater, surface water, ground water or drinking water. We are also working to obtain toxicology data from available sources, including other federal agencies and exploring ways to improve the understanding of potential effects of exposure to contaminants of emerging concern in water.

This type of information can be very useful to EPA to identify potential contaminants for unregulated contaminant monitoring, revising effluent guidelines, and determining which contaminants are the highest priorities for development of new or revised water quality criteria. We will compile the information we receive with the goal of sharing best practices and encouraging broad adoption of effective programs across the country.

EPA is also coordinating research efforts with other federal agencies as part of the Pharmaceuticals in the Environment workgroup and the Endocrine Disruptors in the Environment workgroup, under the auspices of the White House's National Science and Technology Council Committee on Environment and Natural Resources Toxics and Risk Subcommittee. The goals of these workgroups are to identify current federal efforts, avoid duplication of effort, leverage existing resources, and better prioritize Federal efforts. EPA co-chairs both of these workgroups.

EPA is also participating in a World Health Organization (WHO) task force investigating pharmaceuticals and personal care products in drinking water. WHO plans to address a variety of issues such as environmental occurrence and sources of pharmaceuticals and

personal care products in finished drinking water and source water; approaches to assess health risks to vulnerable populations; environmental chemistry of pharmaceuticals and personal care products in natural waters; and advances in treatment methods (including treatment effectiveness) and analytical methods.

My office recently hosted a series of four stakeholder meetings with wastewater and drinking water utilities, state environmental and public health departments, key members of the environmental community, and several agricultural organizations. These meetings helped us better understand what our stakeholders are doing to assess and appropriately respond to pharmaceuticals and personal care products (PPCPs) in our waterways, and identify or build upon opportunities to collaborate. Input from our stakeholders was extremely useful and helped to inform our recently announced new initiatives.

Using Regulatory Tools

We recognize stewardship activities alone may not always be sufficient to manage issues associated with contaminants of emerging concern in water. We are also gathering information that will help us assess whether regulatory action is warranted.

For example, under the Clean Water Act, EPA establishes technology-based national regulations, termed "effluent guidelines," to limit pollutant discharges from categories of industrial facilities to waters of the United States. As part of the effluent guidelines planning process, the Agency is studying the disposal of unused pharmaceuticals by

certain health care institutions to determine current disposal methods and to identify alternative disposal practices that could reduce or avoid direct or indirect discharge of PPCPs to waterways. EPA initiated this effort in 2007 and issued an Interim Report on Unused Pharmaceuticals in the Health Care Industry in August 2008. To complete the Health Care Industry study, EPA intends to conduct an "Information Collection Request" (ICR) in accordance with the provisions of the Paperwork Reduction Act. The ICR will collect additional information on 1) the factors driving current disposal practices, 2) information on the amount and identities of unused pharmaceuticals currently disposed of via the drain or flushing, and 3) the alternatives to drain-disposal. This important collection effort will cover hospitals, long-term care facilities, hospices and veterinary hospitals and is currently undergoing public comment. The comment period closes November 10, 2008.

EPA is also evaluating whether the potential impact of contaminants of emerging concern, including pharmaceuticals and personal care products that exhibit endocrine disrupting activity or other toxic properties, may require the Agency to consider additional or modified procedures for determining appropriate protective levels for aquatic life. In June, EPA presented a paper to the EPA Science Advisory Board detailing the technical issues and recommendations that may serve as a basis for modifying EPA's existing methodology for establishing aquatic life criteria, in response to contaminants of emerging concern.

Additionally, under the Safe Drinking Water Act, the Agency assesses contaminants for potential drinking water regulation. On February 21, 2008, the Agency released the draft Contaminant Candidate List (CCL 3) for public review and comment. As part of the process to develop the list, the Agency evaluated an extensive list of pollutants, including microbial pathogens, pesticides, chemicals used in industrial products and consumer products and contaminants of emerging concern, such as pharmaceuticals, to identify those that have the potential to occur in drinking water provided by public water systems. The public comment process concluded on May 21, 2008. The Agency is evaluating the comments to inform its decision on which contaminants to include on the final list.

Conclusion

Madam Chairwoman, this committee and EPA share a long-standing commitment to keep our water clean and healthy. We know sound science and information must continue to drive our decisions. EPA will continue in evaluating effects, occurrence, and risk reduction strategies so we can make sound decisions to protect public health and aquatic life. By engaging the full range of public and private partners and by using appropriate regulatory and incentive-based tools, we will ensure continued progress in meeting the goals of the Clean Water Act.

Thank you for this opportunity to describe EPA's important work on contaminants of emerging concern. I would be happy to answer any questions you may have.