TESTIMONY OF
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BEFORE THE
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Good afternoon and thank you for this opportunity to appear before this Committee. I am Benjamin H. Grumbles, Assistant Administrator for Water at the United States Environmental Protection Agency (EPA). I welcome the opportunity to describe EPA's actions to protect our Nation's watersheds and drinking water supplies against chemicals in our waterways, especially those that may affect the endocrine (or hormone) system. This issue was raised recently in connection with the Potomac River and needs to be considered in the context of our mission of protecting water quality, human and aquatic health, and assuring safe drinking water.

We work within a national framework of protecting human health and the environment, and aquatic research, using technology and implementing regulations on a watershed basis -- all driven by a strong emphasis on sound science, transparency, public information, and partnerships. This framework reflects requirements established by Congress under the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), the Food Quality Protection Act (FQPA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA).

Our mission is to better understand the physiological effects of exposure to water-related contaminants in terms of metabolic pathways, modes of action, and dose response relationships. How do these contaminants work in the body, and what concentrations may cause an effect? For example, the function of the endocrine system and its operation with regard to the production, release, transport, or elimination of natural hormones in the body is essential research – particularly with regard to the maintenance of normal cell metabolism, reproduction, development, and/or behavior.

When we look at contaminants in water, including chemicals that may affect the endocrine system, we begin by relating what is identified at different locations, concentrations, frequency, time and duration, and then pose the question what human or aquatic life "critical endpoint" may be affected. Critical endpoints that we routinely evaluate include general toxicity (illness and mortality), neurological impacts, immunological effects, as well as reproductive and developmental impacts.

My testimony focuses on three areas – (1) the statutory framework for regulatory and stewardship action; (2) research to increase our understanding of the scope of the problem; and, (3) identify needed solutions.

STATUTORY AND REGULATORY FRAMEWORK

Clean Water Act: Section 304(a)(1) of CWA requires EPA to develop water quality criteria reflecting the latest scientific knowledge related to the kind and extent of effects on human health and aquatic life from the presence of pollutants in our nation's waters. To date, EPA has developed 120 recommended human health criteria and 45 recommended aquatic life criteria for specific chemicals or classes of chemicals. These national recommended water quality criteria (i.e., numeric pollutant concentrations or narrative guidance), serve as the basis for States and Tribes to adopt water quality standards. These standards are used to assess water quality, provide a baseline for non-point source control strategies, and develop discharge limits in CWA permits for industrial and municipal dischargers and municipal wastewater treatment facilities nationally. EPA recently issued two of these chemical criteria that are directly linked to reproductive and developmental impacts – nonylphenols and tributyltins.

When we develop recommended human health and aquatic life criteria, we focus on the most sensitive endpoint, which may be reproductive and developmental effects or others such as immune effects or cancer. It is important to note that if a contaminant has several critical endpoints, protecting for the most sensitive endpoint (which may be something

other than reproductive effects) will also be protective for reproductive and developmental impacts.

Technologies installed to address one class or group of contaminants may also be effective at removing or controlling other contaminants. For example, public water systems that use powdered carbon, ozone, UV, or chlorine to address other treatment needs, may also be removing some level of contaminants with reproductive or developmental effects. The level of removal depends on the technology and the specific contaminant in question. This is an area that EPA continues to examine and research.

Human Health Criteria

In determining human health criteria, EPA evaluates contaminants based on pollutant concentration, potential exposure, and associated human health effects, such as reproductive and developmental endpoints and the relationship among these factors. In addition, EPA evaluates potential exposure routes such as direct ingestion of drinking water and fish/shellfish consumption. To identify chemicals for which EPA will develop recommended human health criteria, EPA works with a broad range of stakeholders to select chemicals with potential health effects that also may occur in water at high concentrations and frequencies, and set priorities for developing national criteria. As new science and data become available, EPA also periodically reviews existing recommended water quality criteria to determine whether any revisions are needed.

Aquatic Life Criteria

In developing recommended aquatic life criteria, EPA uses toxicity data on growth, reproduction, and mortality endpoints found in the literature as well as solicited from the public. The Agency's 1985 Aquatic Life Criteria Guidelines call for a minimum data set comprised of eight different species from eight different families to represent the diversity of organisms, community structures, and populations found in U.S. waters. We consider acute and chronic toxicity data for the most sensitive life stage (e.g., egg, larval, adult), as well as bioconcentration and bioaccumulation studies. The methodology helps assure that the recommended criteria concentration will be protective of aquatic life and

that a scientifically sound process is in place for adjusting the criteria should there be concerns the criteria are over- or under-protective. The method ensures that chemicals causing adverse reproductive effects – regardless of the cause -- have criteria protective of these endpoints.

To better inform our criteria development efforts, we are working nationally to improve understanding of the prevalence in our waters of pharmaceuticals, which include endocrine disrupting chemicals as a subset. We are conducting a pilot study to investigate the occurrence and concentrations of about 40 pharmaceuticals and personal care product in fish tissue. EPA anticipates completing fish sampling and tissue analysis by mid-2007 and producing a report by the end of 2007. This effort is being supplemented by EPA's Great Lakes National Program Office, in partnership with a number of other Federal and local agencies. They are studying the North Shore Channel of the Chicago River to determine if there is reproductive impairment to resident fish and to estimate effluent and stream concentrations of certain chemicals that could cause such impairment.

Safe Drinking Water Act: Using Clean Water Act tools such as water quality criteria and effluent guidelines, EPA and its partners significantly reduce the levels of chemicals entering drinking water plants. Where surface water is used as a public water supply, an additional multi-barrier system of public health protection measures apply to assure that our cities, towns, and communities have clean and safe water to drink. Under the Safe Drinking Water Act and EPA's national drinking water program, the Agency has issued over 200 Public Health Advisories (13 associated with reproductive and developmental endpoints) and established over 85 Maximum Contaminant Level Goals (MCLGs) to date (11 associated with reproductive and developmental endpoints). MCLGs are used in conjunction with information on validated analytical methods, available treatment technologies, and associated costs and benefits to develop enforceable Maximum Contaminant Levels (MCL) or "standards" that apply to approximately 54,000 community water systems that serve over 270 million people across the nation.

In determining whether a contaminant should be regulated, the SDWA directs the Administrator to consider 1) whether a contaminant may have an adverse effect on human health, 2) whether it occurs, or there is a substantial likelihood that it will occur, in public water systems at frequencies and levels of public health concern, and 3) whether regulation of the contaminant presents a meaningful opportunity for health risk reduction for people served by public water systems. To help answer each of these questions, EPA's Office of Research and Development has major national programs devoted to human health effects research, better understanding of exposure issues, analytical methods development, and treatment effectiveness research. EPA's Office of Water has a program to collect monitoring data on unregulated contaminants from a subset of water systems throughout the country.

Applying this research and data to support EPA's ongoing public health protection rulemaking process is important. But equally important is to assure that existing drinking water standards are updated to reflect new science, and that we are looking ahead to identify new contaminants of concern. There are two mechanisms EPA relies upon to keep existing standards up to date, and to identify future contaminants that may warrant more in depth research and possible drinking water regulation.

The first mechanism is the Six Year Review process. Section 1412(b)(9) of SDWA requires that the Agency review existing national primary drinking water regulations every six years and, where appropriate, revise them to reflect new research and information. As a result of EPA's first review of 69 drinking water standards in 2003, we nominated several presently regulated compounds for new health risk assessments due, in part, to new information on reproductive/developmental impacts. We continue to review more recent science and research to identify any new information on reproductive and developmental impacts that may inform our next six year review and regulatory update process.

Looking to the future, EPA also conducts a Contaminant Candidate Listing (CCL) process on a five year cycle to evaluate unregulated drinking water contaminants.

Section 1412(b)(1) of SDWA requires EPA to publish a list of unregulated contaminants that are known or anticipated to occur in public water systems and may require control through national primary drinking water regulation. We have published two CCLs to date and are implementing recommendations made by the National Academy of Sciences and the National Drinking Water Advisory Council to develop a third CCL list. EPA will be sure to include in this evaluation contaminants associated with reproductive and developmental effects.

FIFRA/TSCA: In addition to programs that manage/regulate releases and uses of existing chemicals (chemicals that are being produced today and have been produced and used for many years), EPA also has a robust review process for new chemicals under both the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). EPA reviews new chemicals and pesticides before they are put on the market and takes appropriate regulatory action to reduce risks or prevent releases in those cases where these new chemicals or pesticides are found to pose unacceptable risks. These review processes are designed to identify problem chemicals and pesticides before widespread production and use and to prevent their introduction into the environment in those cases where risks cannot be effectively mitigated through use restrictions. In both of these programs, EPA's review process includes an evaluation of the likelihood of these new compounds causing reproductive impacts to humans and to fish and wildlife. In this way, EPA is actively working to ensure that new chemicals and new pesticides will not present unacceptable reproductive risks to people or fish and wildlife.

FIFRA/FQPA: The Food Quality Protection Act directed the Agency to develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether pesticides and other chemical substances may have an effect on humans that is similar to an effect produced by naturally occurring estrogen or such other endocrine effect as determined by the Administrator. This was a very tall order, especially considering that when FQPA passed there were no validated test systems available – that is, tests that the scientific community considers reliable and

reproducible for screening endocrine disruptors. To help in this major efort, EPA convened independent panels of experts and other stakeholders, including the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), to examine available tests to determine which ones could be used to set up a reliable screening program. Based on this input, the Agency developed a program that includes a two-tiered system. The first tier will include relatively inexpensive short-term assays designed to identify substances that potentially interact with estrogen, androgen, and/or thyroid systems, followed, if appropriate, by second tier confirmatory testing to determine the effects caused and at what dose level they occur. EPA is working to ensure that the *in vitro* and *in vivo* protocols that comprise the two tiers are optimized and validated so that the information they provide will allow identification of problem substances, and that the assays provide the same results when different laboratories perform them.

A major challenge we are addressing is the apparent need for several different assays to screen for endocrine disrupting effects, as no single assay would cover all hormonal effects of concern. Females and males, for example, have different hormone systems and one assay would not cover both. In addition, a substance could cause hormonal effects by several different mechanisms. No single test is comprehensive enough to provide definitive results in all cases. Therefore, it takes several tests to demonstrate that a substance is not likely to cause harm. We are confident the preparatory work underway at EPA will result in an endocrine disruptor screening program based on sound science and will be reliable and defensible.

EPA continues to use its best efforts to complete validation of these endocrine assays as expeditiously as possible without sacrificing essential scientific quality and integrity. EPA is working closely with the Interagency Coordinating Committee on the Validation of Alternative Methods and the Organization for Economic Cooperation and Development to optimize and validate various endocrine effects test methods to promote international acceptance of these methods.

In the meantime, the Agency is working through existing programs to reduce the risk of exposure to pesticide chemicals that could pose reproductive or developmental risks. Office of Pesticide Programs routinely requires pesticide companies to test food use pesticides to determine if they can cause adverse developmental and reproductive effects. They also evaluate pesticides for a range of potential effects on aquatic life. Tests routinely required include full life cycle studies for fish, early life cycle studies for invertebrates, and developmental and reproductive and developmental toxicity studies for a variety of aquatic organisms. In addition, environmental fate data are required to help determine the likelihood of pesticides moving offsite. All of these data are considered in developing pesticide labels that limit the use of pesticides to reduce their introduction into waterways. In addition, the Agency is required by statute to periodically re-examine its previous safety findings to reflect new data.

RESEARCH

We need the best science available to inform our policies and regulations at the federal and state levels. Research supported by EPA's Office of Research and Development (ORD) is improving our ability to test for endocrine disruptors and increasing our understanding of possible exposure routes and effects these chemicals may have on humans and wildlife. ORD is pursing a research strategy with three goals: to support the Agency's screening and testing program; to continue providing the underlying science on the effects, exposure, and risk management of endocrine disruptors; and to determine the impact of endocrine disruptors on humans, wildlife and the environment.

To support the Agency's screening and testing needs, ORD is developing screening and testing protocols that OPPTS is having validated to use in implementing the Endocrine Disruptor Screening Program mandated by the Food Quality Protection Act.

ORD is also focusing research on improving our understanding of the underlying science for developing methods, models and measures to help OPPTS, OW and other parts of the Agency integrate data on endocrine disruptors into their risk assessments. This research has focused on:

- identifying chemicals and classes of chemicals that are endocrine disruptors and their modes of action;
- developing methods to evaluate the effects of mixtures of chemicals that interfere with the endocrine system by common and different mechanisms of toxic effects;
- characterizing the shape of the dose-response curves; and
- developing approaches to extrapolate results across species.

Equally important for determining the impact of endocrine disruptors is applying the methods and models ORD and others are developing to assess real-world scenarios. This work includes identifying potential sources of endocrine disruptors in the environment with a focus on wastewater treatment plants, concentrated animal feeding operations, drinking water plants, and biosolids

To ensure we have the best current science on endocrine disruptors, ORD is coordinating research both domestically and internationally. Domestically, EPA is working with other federal agencies through an interagency working group on endocrine disruptors, including jointly sponsoring research with the National Institute of Environmental Health Sciences, the National Cancer Institute, and the National Institute for Occupational Safety and Health to support epidemiological studies investigating reproductive and developmental effects of endocrine disruptors. Internationally, ORD led the working group that prepared the 2002 World Health Organization report on 'Global Assessment of the State of the Science of Endocrine Disruptors; co-sponsors workshops with the European Union and Japan; and serves with other countries on committees under the auspices of the Organization for Economic Cooperation and Development to harmonize testing protocol development.

ACTIONS IN THE POTOMAC WATERSHED

In response to recent fish kills and reports of intersex fish, EPA Region III is working to better understand the source of the problem. For example, the region has arranged for ORD to examine the possible stressors in the Potomac watersheds and whether there is any link to intersex characteristics in fish, with initial findings available in January 2007.

Additionally, EPA's Wheeling, West Virginia Field Office took water samples from the South Branch Potomac watershed to determine potential contaminants using whole effluent toxicity tests. More broadly, EPA III, in partnership with the Maryland Department of the Environment, the Virginia Departments of Health and Environmental Quality, the West Virginia Department of Health and Human Resources, and water utility partners in the Potomac Basin created the Potomac River Source Water Protection Partnership (Potomac River Basin Drinking Water Source Partnership). The Partnership's goal is to use the results of source water assessments to guide the development of strategies to prevent pollution from entering the Potomac River which could threaten drinking water quality. Endocrine disruptors and pharmaceuticals are a priority area for the partnership. The partnership is working together to share data as it is developed on these recent discoveries. But the causes are still unknown.

CONCLUSION

In conclusion, Mr. Chairman, EPA has a strong and responsive statutory and regulatory framework to understand, manage and reduce hazards – including reproductive and developmental effects -- posed by chemicals in our waters. We have a targeted research program to develop new assays to test for and improve our understanding of hazards posed by chemicals. And we are responding to emerging contaminants and hazards, such as those that prompted this hearing, within this framework. However, these issues are not easy ones and often require considerably more information than is available, as well as additional analysis as the reports from the Potomac highlight.

Our goal and commitment is to bring good science, transparency, and strong partnerships to bear to find needed answers and solutions to ensure we continue to meet EPA's central goal of protecting water quality, human and aquatic health, and assuring safe drinking water. I will be happy to answer any questions.