

EPA Releases List of EDSP Universe of Chemicals

By

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On November 27, 2012, the U.S. Environmental Protection Agency (EPA) released a document entitled *The EDSP Universe of Chemicals and General Validation Principles*, as well as the list of approximately 10,000 chemicals. This article explains the document and its implications.

Background

EPA developed the Endocrine Disruptor Screening Program (EDSP) to meet the Federal Food, Drug, and Cosmetic Act's (FFDCA) mandate to determine whether certain substances may have an effect in humans that is similar to an effect produced by a "naturally occurring estrogen." The FFDCA requires that all pesticide chemicals be screened, and gives EPA the authority to provide for the testing of other substances. Similarly, the Safe Drinking Water Act gives EPA authority to require chemical testing, and EPA is relying on this authority, in part, in developing the EDSP.

According to EPA, the document is a supplement to the June 2012 *EDSP Comprehensive Management Plan*, which EPA intends to provide strategic guidance and outline critical activities that are planned for the EDSP for the remainder of fiscal year (FY) 2012

through FY 2017. *The EDSP Universe of Chemicals and General Validation Principles* addresses chemicals that may be considered by the EDSP for screening and testing within the five-year time horizon of the *EDSP Comprehensive Management Plan*. EPA states that, given the large number of chemicals that it regulates and that are potentially subject to EDSP screening, it is important to prioritize which chemicals should undergo screening so the chemicals with the greatest potential for interacting with the endocrine systems are evaluated in a timely manner to ensure public and wildlife protection. To this end, according to EPA, the document describes general validation principles for the use of computational toxicology tools for efficient chemical prioritization. The document is available at http://epa.gov/endo/pubs/edsp_chemical_universe_and_general_validations_white_paper_11_12.pdf. The list of chemicals is available at http://epa.gov/endo/pubs/edsp_chemical_universe_list_11_12.pdf.

EPA states that the universe of chemicals potentially targeted for testing under the current five-year time horizon of the *EDSP Comprehensive Management Plan* consists of approximately 10,000 unique chemicals, including approximately 6,000 drinking water contaminants, 1,000 pesticide active ingredients, and 5,000 inert ingredients, with some overlap among the lists. The universe of chemicals identified for the EDSP should not be considered a list of ‘known’ or ‘likely’ endocrine disruptors, according to EPA. In considering this universe of chemicals, EPA intends to develop a prioritization scheme built on the broader, general concept articulated in the National Academy of Sciences *Toxicity Testing in the Twenty-first Century: A Vision and a Strategy*.

In the integrated prioritization scheme, EPA states that it intends to apply both exposure and effect-based methods and consider inherent chemical properties to formulate a process for prioritizing chemicals based on their likelihood to interact potentially with the endocrine system. EPA expects consideration of certain factors to prioritize further candidate chemicals and reduce the number of chemicals for Tier 1 screening under the EDSP to those with a higher potential probability of interacting with the endocrine system.

EPA notes that the universe of chemicals is not a static list of chemicals, but instead “represents a dynamic universe of chemicals that will change over time.” EPA will update the prioritization status of this universe of chemicals with the annual update of the *EDSP Comprehensive Management Plan*, and as new data become available.

EPA notes that the document “does not create or confer legal rights or impose any legally binding requirements on the EPA or any other party.” EPA distributed the document “solely for the purpose of sharing this information with the public, consistent with the EPA transparency objectives.” According to EPA, because it is not intended to serve any other purpose, and should not be construed to represent formal dissemination of any Agency determination or policy, “the information correction process under the agency’s Information Quality Guidelines does not apply to this document.”

Endocrine issues have long been the subject of intense interest and scientific debate. Whether you are an industry or environmental advocate, EPA's new document is an important read.

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