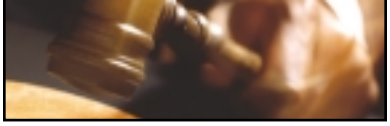

Endocrine Disruptors: The Issue Hits Closer to Home

By Lynn L. Bergeson

The U.S. Environmental Protection Agency (EPA) recently released for comment the approach it intends to use for selecting the first group of chemicals to be screened in its Endocrine Disruptor Screening Program (EDSP).

EPA is following a tiered approach in implementing its mandate under Section 408(p) of the Federal Food, Drug and Cosmetic Act (FFDCA). Section 408(p) directs the agency to develop a screening program to determine whether certain substances might have hormonal effects in humans.

EPA chartered the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) to provide advice and recommendations for developing a strategy to determine whether or not substances have an effect similar to the one produced by naturally occurring hormones. It recommended that EPA address effects on both humans and wildlife; examine effects on biological processes involving the estrogen, androgen and thyroid (EAT) hormones; and include pesticide chemicals, commercial chemicals and environmental contaminants within the scope of the program. Following EDSTAC's recommendations, EPA established the EDSP in 1998.

The core elements of the approach consist of sorting, priority setting, Tier 1 screening and Tier 2 testing.

Tier 1 screening is envisioned as a battery of screening assays that would identify substances with the potential to interact with EAT hormone systems. EPA indicated its intention to select and screen 50 to 100 chemicals to help it refine the screen and then convene an external peer review panel to review the results and assess the screen's integrity.

Tier 2 testing is intended to determine if a substance could cause endocrine effects mediated by EAT-related processes, and to establish a dose-response relationship between an endocrine-active substance and an observed effect.

The proposed approach

EPA's approach for selecting the first group of chemicals focuses on pesticide active ingredients, high-production-volume (HPV) chemicals and some pesticidal inert chemicals.

To select pesticides, EPA will focus on data that demonstrate human exposure by food or drinking water consumption, residential use and occupational contact with pesticide-treated surfaces. The agency will give a higher priority to pesticides likely to pose exposure opportunities by more than one pathway, with those likely to pose exposure opportunities by all four pathways receiving the highest priority.

EPA is proposing a similar approach to identify HPV/inert chemicals. EPA intends to focus on several indicators of the potential for human exposure, including production volume, certain pathways of exposure and the presence of an HPV/inert chemicals in human tissue.

The agency's step-wise approach calls for it to:

- Identify chemicals that are both pesticide inerts and HPV chemicals.
- Identify HPV/inert chemicals that have been found to be present in human tissue, ecological tissues that have human food uses or drinking water/indoor air. EPA will rely on a broad array of databases maintained by it and other federal agencies.

EPA proposes to produce four lists of chemicals, one for each type of monitoring data, and giving a higher priority to chemicals that appear on multiple lists. EPA would give greater priority to chemicals that appear in human biological monitoring data, and drinking water/indoor air, followed by ecological biological monitoring data relevant to humans.

EPA proposes to identify any chemical for which the information "clearly" indicates an "endocrine-mediated effect/perturbation." During this last step, EPA also would dismiss chemicals it would expect to have a low potential to cause endocrine disruption.

Critical stakeholder issues

Critical issues include the integrity of the exposure data on which EPA relies and the lack of an integrated approach to agency chemical testing initiatives.

The exposure databases on which EPA will rely are believed by many to be unreliable and flawed. EPA's proposal also does not account adequately for other programmatic testing priorities.

EPA's proposed approach is expected to have significant impacts on the chemical manufacturing, processing and user communities — virtually all of them adverse. Given the significance EPA is placing on human exposure as a tool to prioritize chemical candidates, the identification of chemicals as "potential" endocrine disruptors almost certainly will have adverse commercial consequences.

Product de-selection and toxic tort litigation are two consequences that come immediately to mind for consumer products containing chemicals suspected — not proven — of endocrine disruption potency. Many business sectors will be affected directly and adversely by EPA's regulatory actions in this area. Readers are urged to comment on this regulatory initiative and help ensure EPA's final selection strategy is focused, defensible and reasonable. **CP**

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