Legal Lookout: Endocrine Disruptors: Test Orders Abound

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As EPA plans to require chemical screening, industry is concerned how the information will be released and possibly misinterpreted.

In April 2009, EPA identified a final list of 67 chemicals for initial screening under the Endocrine Disruptor Screening Program (EDSP). From October 2009 to April 2010, the agency issued more than 700 test orders. Responding to an EDSP test order can present challenging issues. The agency began implementing this mandate well over a decade ago through the EDSP.

Later this year, another 100 chemical substances may be added for screening.

Test orders

Under EDSP, EPA has created a two-tier testing approach. Tier 1 screening is intended to identify substances with potential to interact with estrogen, androgen or thyroid hormone systems. Tier 2 testing establishes a dose-response relationship for adverse effects resulting from interactions identified through the Tier 1.

Each Tier 1 test order recipient must respond to EPA within 90 days of issuance. Recipients may select from several options, which vary between those that are pesticide registrants and those that manufacture or import a pesticide inert ingredient. The recipient can indicate that it:

* Intends to generate new data;
* Is submitting or citing existing data (including other scientifically relevant information);
* Intends to form (or offer to form) a consortium to provide data; or
* Is not subject to the test order.
* A pesticide registrant can indicate that it:
* Intends to voluntarily cancel any pesticide registration to which the order relates;
* Intends to reformulate its products to exclude the chemical; or
* Is claiming a formulator's exemption.

A pesticide inert ingredient manufacturer can indicate that it:

* Has discontinued or is in the process of discontinuing manufacture or importation of the chemical;
* Does not and will not sell the chemical for use in pesticide products;
* Can demonstrate that the chemical is an endocrine disruptor and additional screening or testing under EDSP is unnecessary;
* Is requesting an exemption based on hazard-related information indicating that the chemical is not an endocrine disruptor; or
* Is offering another response, such as challenging the order or asking EPA to reconsider.

Test orders will include a final submission due date of 24 months after issuance.

Practical implications and key issues

Recipients must decide early which response options noted above to select. Many recipients are uncertain as to what some of the options mean. For example, how does a recipient demonstrate that it does not and will not sell the chemical for use in pesticide products?

There continues to be controversy over whether Tier 1 screening assays are scientifically defensible. Because the state-of-the-science in this area is new, the controversy over the probative and scientific value of the Tier 1 screens is expected to continue. EPA said it is developing tools it needs to interpret the screening results and ensure consistency in its decision-making.

Managing the optics of the EDSP is a challenge. Industry stakeholders from the beginning have been concerned about the implications of having their chemicals identified as Tier 1 screening test substances. EPA has consistently maintained that merely screening a substance for endocrine effects does not mean, and should not be interpreted to mean, that the substance is an endocrine disruptor.

Many industry stakeholders question whether EPA and other governmental bodies will carefully and consistently qualify what the test results mean, and do not mean. PE