Legal Lookout: Endocrine Disruptors: Test Orders Abound

By

Lynn L. Bergeson[1]

In April 2009, the U.S. Environmental Protection Agency (EPA) identified a final list of 67 chemicals for initial screening under the Endocrine Disruptor Screening Program (EDSP). As of April 2010, EPA had issued over 700 test orders since October of last year for these 67 chemicals. How recipients respond to an EDSP test order can present challenging issues, and this article explains why.

Background

Under Section 408(p) of the Federal Food, Drug, and Cosmetic Act, EPA is required to develop a screening program to determine whether substances may have hormonal effects in humans. EPA began implementing this mandate well over a decade ago through the EDSP.

The 67 chemicals include certain pesticide active ingredients and high production volume (HPV) chemicals used as pesticide inert ingredients. EPA selected these chemicals because each was determined to be present in at least three of four exposure pathways. EPA is expected later this year to identify another 100 chemical substances for screening under the EDSP.

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Test Orders

Under the EDSP, EPA has created a two-tier testing approach. Tier 1 screening is intended to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. Tier 2 testing is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays.

Each recipient of a Tier 1 test order is directed to provide an initial response to EPA within 90 days of issuance of the order. For purposes of making this initial response, test order recipients may select among several options, and the options vary between those recipients that are pesticide registrants and those recipients 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.

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- A pesticide registrant can indicate that it:

  - Intends to voluntarily cancel any pesticide registration to which the order relates;

  - Intends to reformulate its product or 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

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- Is offering another response, such as challenging the test order or asking EPA to reconsider some or all of the testing specified in the order if certain conditions are met.

The recipient may indicate a different response commitment for each assay. Test orders will include a "final submission" due date of 24 months after issuance of the order.

Practical Implications and Key Issues

Receipt of a test order raises issues. First, recipients must decide early on how best to respond. Recipients will have to choose among the response options noted above, and care will need to be taken to select the correct approach. Many recipients of test orders that are not pesticide active ingredients 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? Other questions have arisen and EPA is expected to clarify certain issues in this regard.

Second, there continues to be controversy over whether the EDSP 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 has stated that it is developing the tools it needs to interpret the screening results and ensure consistency in Agency decision-making. These tools include a weight-of-the-

evidence approach and standard evaluation procedures (SEPs). The lack of clarity regarding the SEPs and the fluidity of the process only heighten industry stakeholder concerns. Stakeholders are particularly concerned about how EPA plans to interpret and communicate screening results, and the process the Agency will use to do so.

Third, managing the "optics" of the EDSP is a challenge. Since the inception of the EDSP, industry stakeholders 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.

That said, however, manufacturers, importers, processors, and users of chemicals identified for screening are concerned about how information on the EDSP and test results from the program are communicated to the public. Many industry stakeholders question whether EPA and other governmental bodies will carefully and consistently qualify what the test results mean -- and do not mean.

Conclusion

EPA's recent issuance of test orders for Tier 1 screening is a major milestone in the EDSP. This step will force much hard thinking by order recipients, who will have to select a response and develop a communication strategy. Selecting the appropriate response requires

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business savvy, technical finesse, and a clear understanding of the legal implications of each alternative.

[1] Lynn L. Bergeson is Managing Director of Bergeson & Campbell, P.C., a Washington, D.C. law firm focusing on conventional and engineered nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues, and President of The Acta Group, L.L.C. and The Acta Group EU, Ltd with offices in Washington, D.C. and Manchester, UK.

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