Attachment 2.

Concerns Regarding EDSP and Requirements of TSCA 8(e) and FIFRA 6(a)(2)[1]

EPA provided very limited guidance to companies regarding TSCA 8(e) reporting of endocrine screening test results in its 1998 EDSP Policy Statement.2 However, no additional TSCA 8(e) guidance on this topic has been provided by EPA since that time. In the 1998 Policy Statement, EPA addressed in vitro assays, and indicated that results from such in vitro assays alone would not be required to be submitted under TSCA 8(e) or FIFRA (6)(a)(2).

> *"EPA will likely adopt as part of its EDSP both in vitro and in vivo assays that assess selected hormonal endpoints. Based on the current state of the science, EPA considers the results of endocrine disruptor in vitro screening assays to be indicators of potential endocrine activity. Whether performed at the bench or in a high throughput mode, results from in vitro assays may suggest some mechanisms of endocrine activity (e.g., hormone receptor binding, binding plus transcription, cell proliferation, steroidogenesis, etc.). Thus, the results of these in vitro assays are arguably within the scope of TSCA section 8(e) and FIFRA section 6(a)(2). At this time, however, EPA cannot conclude that the results of these in vitro assays translate into an understanding of particular health or environmental hazards and risks in vivo. Therefore, based on the current state of the knowledge, EPA will not, at this time, require submission of TSCA section 8(e) or FIFRA section 6(a)(2) reports containing only the results of these in vitro assays. Registrants, manufactures, or importers are, nevertheless, encouraged to submit the data voluntarily*."

However, in this 1998 Policy Statement, EPA went on to state:

> *"If these test results are included with other information reportable under TSCA section 8(e) or FIFRA section 6(a)(2), then they must be reported."*

EPA has provided no additional guidance on the EDSP and compliance with TSCA 8(e) and FIFRA 6(a)(2) since publication of this 1998 Policy Statement.

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[1] Prepared by Richard A. Becker, Ph.D., DABT, American Chemistry Council, 5/18/09

[2] Endocrine Disruptor Screening Program: Statement of Policy; Federal Register / Vol. 63, No. 248 / Monday, December 28, 1998 /71542 -71568. The following provides EPA's guidance on the reporting obligations under the TSCA section 8(e) and FIFRA section 6(a)(2) with respect to results from certain priority-setting studies and *in vitro* screening assays that industry or others may conduct voluntarily or as part of EPA's EDSP. TSCA section 8(e) requires that "[a]ny person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform [EPA] of such information" (15 U.S.C. 2607(e)). Likewise, FIFRA section 6(a)(2) requires registrants that, after registration of a pesticide, have additional factual information regarding unreasonable adverse effects on the environment of the pesticide to submit the information to EPA (7 U.S.C. 136d(a)(2)).

Therefore, since the EDSP Tier 1 battery proposed by EPA contains both in vitro and in vivo tests, having the SEPs and WOE criteria in hand before such EDSP Tier 1 data would provide companies with the necessary interpretation procedures to assist in determining the combination of in vitro and in vivo results that indicate a need to immediately report to EPA in accordance with requirements of TSCA 8(e) and FIFRA 6(a)(2).

Moreover, information reported to EPA in accordance with TSCA 8(e) is made public essentially in real time by posting on its public web site:

> *"EPA is posting TSCA Section 8(e) and FYI submissions to the Agency on this website for the purpose of making them more easily accessible to the public. EPA has not evaluated these submissions prior to posting and cannot attest to their accuracy or completeness" (http://www.epa.gov/opptintr/tsca8e/pubs/8eandfyisubmissions.htm)*

EPA must also develop and promulgate harmonized test guidelines for use in the development of test data for submission to the Agency (see EPA's Harmonized Test Guidelines http://www.epa.gov/opptsfrs/home/guidelin.htm). Yet for the EDSP, EPA has not yet published draft test guidelines nor adopted final test guidelines for any of the Tier 1 EDSP screening methods. Nevertheless, the Agency intends to impose FIFRA and TSCA penalties for lack of compliance with EDSP procedures.

> *"Test guidelines are documents that specify methods that EPA recommends be used to generate data to support the registration of a pesticide, setting of a tolerance or tolerance exemption for pesticide residues, or the decision making process for an industrial chemical. These data are used by the Agency to perform risk assessments and make regulatory decisions."*
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> *"Studies conducted according to these test guidelines may be required under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136) for pesticide registration. The guidelines may also be useful for satisfying FIFRA data requirements in 40 CFR part 158 and part 161, data-call-ins issued pursuant to FIFRA section 3(c)(2)(B), as needed to satisfy data requirements appropriate for specific pesticide registration applications, or for satisfying data requirements to demonstrate the safety of a tolerance or tolerance exemption under section 408 the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a)."*
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> *"Test guidelines used in regulatory actions as bases for test standards under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601) are typically promulgated in 40 CFR part 799, or may be written into specific TSCA rules (such as test rules under TSCA section 4). The test guidelines may also be used as part of voluntary testing. Note that where data will be required under a TSCA rule (such as a test rule under TSCA section 4), a TSCA-specific version of the applicable guideline may be promulgated as a rule. Examples may be found at 40 CFR part 799, subparts E and H."*