SAP Overview and Charges

Overview:
The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) is requested to provide advice that will inform the Environmental Protection Agency (EPA) of its next course of action regarding an *in utero* through lactational assay as a potential screening tool in the Endocrine Disruptor Screening Program (EDSP) Tier-1 battery for assessing the effect of chemicals on the endocrine system. Specifically, the SAP is asked to consider three options under consideration by the EPA: 1) continuing development and validation of the assay under the current proposed protocol (Protocol C), 2) continuing development and validation of the assay under a modified or alternative protocol, or 3) suspending the present course for the development and validation of an *in utero* through lactational assay as an EDSP screening assay in the Tier-1 battery.

In developing responses to the specific charge questions, the SAP is asked to consider previous information primarily from the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), Science Advisory Board and Scientific Advisory Panel (SAB/SAP) and Detailed Review Paper (DRP) as well as more contemporary information as follows: 1) Results of the feasibility study with methoxychlor and practicality of Protocol C, 2) Research status of chemical exposure *in utero* and during lactation and the cursory comparison of the results between the *in utero* through lacatational assay and the uterotrophic, pubertal and adult male assays in response to treatment with methoxychlor and other chemicals, and 3) Consideration to replace the current 2-generation reproductive toxicity test with a Life-Stages Developmental and Reproductive test enhanced to detect endocrine effects in the EDSP Tier 2 which may, therefore, obviate the need for a comprehensive endocrine-specific *in utero* through lactational assay in Tier 1.

Specific charges:
1) Considering the current biology and logistics, time, cost and other resources involved in conducting an *in utero* through lactational screening assay, please comment on the need, strengths, weaknesses and practicality of developing and validating the bioassay as an EDSP Tier-1 screen.

2) Please comment on the basis for supporting continued development and validation of an *in utero* through lactational screening assay using Protocol C in the EDSP Tier-1 battery.

3) Please comment on the basis for supporting development and validation of a revised Protocol C or alternative Protocols A or B or some other protocol for an *in utero* through lactational screening assay in the EDSP Tier-1 battery. What are the strengths and weaknesses of a revised Protocol C or alternative protocols and would this revised *in utero* through lactational screening assay be considered an alternative assay, if so, replacing what assays, or an additional assay in the EDSP Tier-1 battery?

4) Please comment on the basis for supporting suspension of the present course for development and validation of the *in utero* through lactational assay as an EPA screening assay in the EDSP. What research would be useful in developing an *in utero* through lactational assay that would support reconsideration of the bioassay as a screen in the Tier-1 battery?