Reference Chemicals Used in EDSP Tier 1 Prevalidation Studies

Prepared for the Endocrine Methods Validation Subcommittee
August 19,2003

NOTE: The chemicals contained in this document were selected as reference chemicals for prevalidation studies in the EDSP assay validation program because they produced a well-documented positive response in one or more Tier 1 assays by an identified mode of action. Some chemicals may act by more than one mode of action. It should be noted that this is **not** intended to be a list of endocrine disruptors, and it should not be concluded a chemical on this list is necessarily an endocrine disruptor since that designation also requires an association with an adverse effect identified in a Tier 2 study. Although some chemicals on this list have been studied extensively, others have not been studied in tier 2 assays.

For the most part, test results from the literature have not been included in these tables as such studies raise questions about comparability of protocols and data. Thus, the entries in the tables represent studies conducted in the EDSP validation program, EPA ORD laboratories, and the OECD assay validation program. The exception to this are the studies shown for the adult or intact male assay, which was developed by the US chemical industry and tested in various industry laboratories.

The chemicals used in prevalidation appear in the following tables grouped into five modes of action: estrogen receptor binding, androgen receptor binding and 5"-reductase inhibition, inhibition of steroidogenesis, inhibition of aromatase, and neuroendocrine. Some chemicals appear more than once because they act by more than one mode of action.

Questions for the EDMVS Regarding Reference Chemicals

1. Does the EDMVS agree with the EPA's decision to limit consideration of data to the studies conducted in the EDSP validation program, EPA ORD laboratories, the OECD assay validation program, and for the adult male, the US chemical industry laboratories?

2. The ensure that the assays selected to comprise the tier 1 battery cover the known modes of action in a comprehensive, complementary and efficient fashion, EPA has grouped the chemicals used in prevalidation into five modes of action. How many chemicals should be selected to compare assays across modalities?

3. What additional chemicals should be chosen for specific assays during validation to facilitate comparisons?