

OECD GUIDANCE DOCUMENT NEUROTOXICITY TESTING

- ▶ PMRA LED INITIATIVE
- ▶ PROVIDES DIRECTION, RATIONALE FOR WHEN/HOW NEUROTOXICITY TESTING SHOULD BE CONDUCTED
- ▶ GUIDANCE SPECIFIC TO ADULT ANIMALS
- ▶ PMRA STATUS
- ▶ FINAL DRAFT COMPLETED OCT 1999
 - ◆ TO BE PUBLISHED UNDER OECD ENVIRONMENTAL HEALTH AND SAFETY PUBLICATION SERIES ON TESTING AND ASSESSMENT



DEVELOPMENTAL NEUROTOXICITY TEST PROTOCOL

- ▶ DRAFT PROTOCOL DEVELOPED
 - ◆ LARGELY BASED ON EXISTING EPA TEST PROTOCOL
- ▶ NUMBER OF OUTSTANDING SCIENTIFIC QUESTIONS REQUIRED RESOLUTION - VIA EXPERT WORKING GROUP (ILSI)



DEVELOPMENTAL NEUROTOXICITY TEST PROTOCOL

Cont'd

Example:

- ◆ BEHAVIOURAL TESTING
 - ◆ NEUROPATHOLOGY REQUIREMENTS
 - ◆ PHARMACOKINETICS

 - ◆ DIRECT DOSING OF PUPS
 - ◆ EXTENSION OF DOSING PERIOD
- ▶ WG HAS PROVIDED COMMENTS TO OECD



DEVELOPMENTAL NEUROTOXICITY TEST PROTOCOL

Cont'd

- ▶ PMRA STATUS
- ▶ PARTICIPATED IN DISCUSSIONS AND PROVIDED COMMENTS ON PROTOCOL
- ▶ AWAITING OECD TO MOVE DRAFT TO COMMENT PHASE
- ▶ UNTIL PROTOCOL FINALIZED - PMRA UTILIZES EPA PROTOCOL

