Intro and Background
Session III: Models - Residential Exposures - REx Model

Passage of the Food Quality Protection Act in 1996 necessitated significant revisions to EPA's risk assessment policies, guidance documents and associated models for estimating exposure and risk to pesticides.

REx is a **R**esidential **Ex**posure Model which automates the calculations required to estimate exposure and associated risk from residential use(s) of pesticides. The REx model reflects a meaningful advancement to software currently available to EPA's Office of Pesticide Programs for estimating residential exposure and risk to pesticides. As such, EPA is soliciting SAP comments and peer review of the REx Model (version 2.1G) and advice on how to proceed with future revisions of the model. To assist the SAP in their review of REx each panel member was provided:

- This background document
- CD containing:
  - REx Model
  - REx Technical Notes
  - REx Turf Case Study
- Questions for the SAP

Rex Model-summary description: REx is a software tool, developed by the Non-Dietary Subcommittee of the OP Case Study Group, for routine deterministic and/or stochastic estimation of potential applicator and post-application residential exposures for a variety of common product use categories (those addressed in the EPA's Standard Operating Procedures for Residential Exposure Assessment).

REx is a tool designed to provide screening-level and, if data are available, refined estimates of aggregate residential exposure, absorbed dose and risk. REx was developed as customized spreadsheets using Visual Basic for Applications (VBA) and Microsoft Excel providing ease of use by a broad community of end-users. The REx CD ROM includes scientific literature review documents, a case study (residential turf scenario), help files and transparent documentation of all modeling algorithms and associated input variables (technical guidance).

The REx structure is transparent and extremely flexible. It facilitates iterative calculations, quality assurance reviews, reproducibility of assessments, standardized reporting of input

variable values for each scenario selected, and several output formats. The Visual Basic for Applications (VBA) programming platform and modular design of REx also facilitates rapid and cost-effective additional customization (e.g., addition of alternative assessment method algorithms, outputs or reports, etc.). REx has been used to respond to EPA draft REDs and FQPA aggregate assessments related to registration and re-registration under the Food Quality Protection Act (FQPA). In addition, ORETF (Outdoor Residential Exposure Task Force) provided support for the development of REx and is creating a customized version that will be supplemented with proprietary data.

REx provides a multi-pathway, multi-route modeling approach and includes multiple assessment methods (e.g., post application whole-body dermal transfer coefficients and/or unitless body-part-specific transfer factors). It allows the risk assessor to examine exposure values for selected applicator or post-application scenarios and considers inhalation, dermal, and incidental ingestion routes. Multiple subpopulations are addressed simultaneously. Exposure factors associated with these subpopulations can be customized by the user. Further, the default scenarios and algorithms currently specified in the EPA Standard Operating Procedures for Residential Exposure Assessment are included as optional selections in REx. Additionally, alternative algorithms and input variable values based on a comprehensive review of the scientific literature are options within REx. Results of the literature review and other documents are also provided on the REx CD ROM.

REx provides a credible basis to understand relative similarities and differences regarding potential post-application exposure across pesticidal active ingredients, formulations, product categories, pathways, routes, and overall aggregate exposure and risk. Thus, Margins of Exposure (MOEs) can be derived in the most biologically relevant manner (e.g., route-specific MOEs versus total systemic dose-based MOE).

The current version of REx provides estimates for day-of-application exposures. Exposures may also be estimated for individual post-application days, i.e., in cases where media-specific decay or "exposure decline" half-life values are available.

Advancements to REx are also near completion to accommodate Industry task force data as inputs to modeling, including applicator "unit exposure" distributions, and product use/usage survey data (e.g., frequency and timing of use events) to

facilitate derivation of calendar-based exposure profiles and associated moving-averages for time periods relevant to the toxicological effects of interest.

The generic version of REx is based on publicly available data. However, REx can accommodate proprietary data and associated input variable values as alternatives. REx has been submitted for review by the U.S. EPA, California DPR and Health Canada\rquote s PMRA and individuals with relevant expertise in the European Union. REx represents the culmination of more than two years of consensus-building processes and thus, reflects the current state-of-knowledge with respect to residential exposure assessment methods.

Finally, REx provides a means for understanding the biases (e.g., conservatism) associated with the application of data from different exposure monitoring study designs for applicators or post-application activities (e.g., passive personal dosimetry data from choreographed studies, such as “jazzercise” versus biomonitoring survey data) and thus, facilitates comparisons, validation and weight-of-evidence considerations to support expert opinion or professional judgement, where it is necessary