

PROJECT SHEET

SUBCOMMITTEE: Food Residue

PROJECT TITLE: **Dietary Exposure Assessment (Methodologies)**

PROJECT ID: FR04-03-1005

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GOAL: To promote learning exchange in the areas of residue chemistry and dietary exposure assessment between regulators.

PROJECT DESCRIPTION:

The United States and Canada perform various types of risk assessments to evaluate the safety of pesticides in food, including analyses to determine the nature and the amounts of pesticides that people might be exposed to over a single day, over multiple consecutive days and over a life time. Exposure estimations are determined for general populations as well as many subpopulations (infants, children, teenagers, adults, seniors, etc.).

Canada and the United States have ongoing *ad hoc* bilateral cooperation in this area as a result of the Joint Review activities. For the most part, PMRA and EPA have harmonized dietary risk assessment methodologies for the determination of exposure of food residues, which assists in these Joint Review activities. The PMRA has used, to the greatest extent possible, the policy and guidance outlined in United States Environmental Protection Agency (EPA) documents, including *Available Information on Assessing Exposure from Pesticides in Food—A User's Guide* (EPA 2000), to harmonize dietary risk assessment procedures for determining the safety of pesticide residues in domestic and imported treated foods.

Though it can be argued that there is overall congruence in risk estimation methodologies, many scientific and policy considerations involved in carrying out these risk assessments are not readily appreciated. Some examples are as follows:

- how to perform dietary burden calculation for animal commodities and secondary animal foods such as apple pomace;
- incorporating residues in imported foods and feeds into dietary risk considerations;
- selecting appropriate refinement strategies, e.g., using Pesticide Data Program and market basket surveys, compliance monitoring data, less than limit of detection in data packages, percentage crop treated, estimation of market share as surrogate information etc.;
- a variety of issues relating to probabilistic dietary risk estimation methodologies.

The process for aggregating food and water plus non-occupational exposure in the risk assessments also requires consideration and consultation among regulators. In addition, risk assessment methodologies are evolving in both the United States and Canada, with both countries moving increasingly toward more fully aggregating risks using probabilistic methodologies. It is important that communication occur regarding changing and updating dietary risk assessment methodologies to ensure that harmonization is maintained.

WORK PLAN:

The Work Plan will be further developed as issues and areas of common interest are identified. The initial goal is to promote learning exchange between regulators and to facilitate the intra-NAFTA exchange of scientific knowledge need to carry out dietary exposure health risk assessments. To this end, a series of quarterly conference calls will be arranged on various topics of mutual interest (see Appendix I, References for Facilitating the Learning Exchange). These topics may include upcoming science and science policy issues that are continually evolving, more detailed description of previously issued science policy documents and issues surrounding their implementation, or current exposure assessment practices.

APPENDIX I References For Facilitating the Learning Exchange

Novigen Sciences, Inc. 2000. Background material for the March 2000 FIFRA Scientific Advisory Panel Meeting. Background document for the sessions: dietary exposure evaluation model (DEEM™) and DEEM™ decompositing procedure and software. February 29 to March 3, 2000.

Pest Management Regulatory Agency. 1998. Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*. Health Canada, Pest Management Regulatory Agency, Ottawa, Ontario.

Pest Management Regulatory Agency. 1998. Regulatory Directive DIR98-02, *Good Laboratory Practice*. Health Canada, Pest Management Regulatory Agency, Ottawa, Ontario.

Pest Management Regulatory Agency. 2003. Science Policy Notice SPN2003-02, *Assigning Values to Nondetected/Nonquantified Pesticide Residues in Foods*. Health Canada, Pest Management Regulatory Agency, Ottawa, Ontario.

Pest Management Regulatory Agency. 2003. Science Policy Notice SPN2003-03. *Assessing Exposure from Pesticides in Food A User's Guide*. Health Canada, Pest Management Regulatory Agency, Ottawa, Ontario.

United States Food and Drug Administration. 1994. *Pesticide Analytical Manual*. Volume 1. Multiresidue Methods. 3rd edition (Revised September 1996, October 1997 and October 1999). United States Government Printing Office, Washington, District of Columbia.

United States Food and Drug Administration. 1997. *Pesticide Analytical Manual*. Volume 2. Individual Residue Methods. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1991. *Guidelines for the Use of Anticipated Residues in Dietary Exposure Assessment*. March 25, 1991. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1996. *Residue Chemistry Test Guidelines OPPTS 860-1000 Background*. Document Code EPA 712-C-96-169. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1998. Memorandum from Margaret Stasikowski to Jim Jones, Anne Lindsay and Lois Rossi. "Supplementary Guidance on Use of OPPTS Residue Chemistry Test Guidelines 860.1500, Crop Field Trials (Residue Zone Maps - Canadian Extension)". April 8, 1998. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1998. *Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs*. Draft document (63 FR 59780). United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1999. *Guidance for Performing Aggregate Exposure and Risk Assessments*. Draft document (65 FR 459). United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1999. Memorandum from Margaret Stasikowski, Director Health Effects Division to Health Effects Division Staff. "Classification of food forms with respect to level of blending. HED Standard Operating Procedure 99.6 (8/20/99)". August 20, 1999. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1999. The Role of the Use-related Information in Pesticide Risk Assessment and Risk Management. Draft document (64 FR 37977). United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1999. Background document for the May 26, 1999, meeting of the FIFRA Scientific Advisory Panel. Statistical Methods for Use of Composite Data in Acute Dietary Exposure Assessment. May 26, 1999. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 1999. Memorandum from Margaret Stasikowski, Director Health Effects Division to Health Effects Division Staff. "Translation of monitoring data. HED Standard Operating Procedure 99.3 (3/26/99)". March 26, 1999. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 2000. Background document for the March 1, 2000 meeting of the FIFRA Scientific Advisory Panel. Office of Pesticide Programs' Comparison of Allender, RDFgen, and MaxLIP decomposition procedures. February 1, 2000. United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 2000. *Guidance for Refining Anticipated Residue Estimates for Use in Acute Dietary Probabilistic Risk Assessment*. (65 FR 39147). United States Environmental Protection Agency, Washington, District of Columbia.

United States Environmental Protection Agency. 2000c. *Assigning Values to Non-detected/Non-quantified Pesticide Residues in Human Health Food Exposure Assessments*. (65 FR 17266). United States Environmental Protection Agency, Washington, District of Columbia.