APPENDIX I - DATA REPORTING GUIDELINES

I.1 INTRODUCTION

This Appendix provides a summary of the particular types and amounts of data that should be included in study reports. The types of data generated under Series 875, Group B include, but may not be limited to, the following:

- Pre-Field Data;
- Field Notes;
- Climatological Data;
- Characterization Data;
- Analytical Methodologies;
- Quality Control Data; and
- Residue Data/Results.

Critical data reporting requirements are discussed below. The Agency encourages investigators to provide data both electronically (e.g., standard commercially available spreadsheets such as Lotus, Quattro Pro, or Excel) and in hard copy. Data provided in electronic format may ease the Agency's review efforts by eliminating the data entry step and, therefore, may expedite the reregistration process. Where possible, each specific datapoint should be entered as an individual piece of information (i.e., individual cell in a spreadsheet).

I.2 DATA REQUIREMENTS

I.2.1 Pre-field Data

Any data that are critical to the design and implementation of a study must be reported in any submission to the Agency. Pre-field data may include the following:

- Detailed Product Use Information;
- Reentry/Postapplication Human Activity Pattern Information;
- Environmental Fate and Transport Data;
- Product Chemistry Data;
- Toxicity Data;
- Sampling and Analytical Methodology;

- Dosimeter Selection Criteria;
- Dosimeter Preparation Data;
- Crop/Crop Group Selection Criteria;
- Site Selection Criteria; and
- Application Selection Criteria.

In general, the types of data described above will not require significant manipulation prior to use by the Agency. A succinct narrative that summarizes the data should be provided along with the raw data (e.g., product use information, fate and transport data, product chemistry data, toxicity data, and analytical methodology). Any data used as a reference in this section (e.g., fate and transport data, product chemistry data, toxicity data) that have been submitted to the Agency for other reregistration purposes must be clearly identified by the appropriate Agency coding system (e.g., Master Record Identification (MRID) Number).

I.2.2 Field Notes

Field notes are a critical component to the successful completion of any study. Field notes should describe, in detail, all activities that occur during the field phase of a study. Field notes may include information pertaining to the following:

- Study Site Description and Map;
- Lot/Batch Numbers for Test Substance;
- Description of Individual Test Subjects (e.g., height, weight, years of experience, name, etc.);
- Exposure Monitoring Interval (i.e., time of day, duration, etc.);
- Timing of Dislodgeable Residue Sampling and Exposure Monitoring;
- Calibration Data for Application Equipment and Monitoring Devices;
- Field Recovery Sample Descriptions;
- Descriptions of Dosimeters, Personal Clothing and Protective Clothing/Equipment;
- Observations on Work Practices;
- Sample Locations in a Treated Area;
- Description of Sampling Equipment;
- Sample Storage and Shipment;
- Comments not Described in the Fields Above; and
- Any Protocol Deviations.

Several types of data included in the list above may be reported electronically as well as in hard copy. Map/site descriptions should be as detailed as possible. All data collected that are specific to each test

subject may also be reported in electronic format (e.g., exposure interval, personal monitoring pump calibration data, lot/batch number of end-use-product, and clothing/dosimeter scenario).

I.2.3 Climatological Data

Climatological data should be reported for the entire study period. They may be collected on-site using appropriate instruments, or the data may be acquired from a variety of offsite sources. Most instruments currently used by investigators are not capable of generating data in an electronic format (e.g., the only way to retrieve the data is to read a meter and record the datapoint in a log book). Also, data retrieved from offsite sources such as NOAA (National Oceanic and Atmospheric Administration), may not be available electronically. However, climatological data may be reported in electronic format, if possible. Such data may include the following:

- Wind speed and direction;
- Solar Radiation;
- Temperature (Air);
- Relative Humidity;
- Description of Weather Events and Irrigation Practices, including measurement of daily rainfall and total rainfall during the study period;
- Residential Practices (e.g., HVAC Set Points and Window Use);
- Industrial/Commercial Practices (e.g., Greenhouse Fan/Shade Cloth and Ventilation Practices); and
- Specific Descriptions of Monitoring Equipment.

Means, medians, and ranges for all appropriate data fields should be calculated and submitted (e.g., temperature and relative humidity over specific exposure intervals and/or study days).

I.2.4 Characterization Data

Characterization data may be supplied by investigators for the test substance, study soils, and water samples. Characterization of the test substance is a requirement of the Good Laboratory Practices (GLPs). Unless a significant number of lot/batches are used in a specific study, electronic reporting of this data is not required. This is also true for soil and water characterization data unless a significant number of sites are utilized in a study. Typically, test substance characterization data include a description of the analytical procedure, raw data (e.g., chromatograms), and the results. Soil and water characterization data usually include several parameters (e.g., texture, pH, etc.).

I.2.5 Analytical Methodologies

Analytical methodologies should be developed and validated according to the guidance included in Series 875, Group B and Residue Chemistry Methods 860.1340, and PR Notice 96-1. All results should be reported on the basis of sample matrix. For each matrix, the following summaries of the raw data must be provided:

- Description of the analytical methodology;
- Quantification and detection limits for all matrices and how each value was determined;
- Means for all samples;
- Standard deviations (σ) for all samples;
- Number of replicates per calculation (n) and reason(s) for excluding any datapoints;
- Coefficients of variation (C.V.) for all samples; and
- 95 percent confidence interval (upper and lower limits) at a minimum over all fortification levels.

I.2.6 Quality Control Data

Historically, the most common study deficiency that resulted in rejection of post-application exposure studies has been the lack of adequate quality control data. Various types of quality control data have been previously defined in this document. These data include, but are not limited to, the following: field recovery, laboratory recovery, storage stability, and travel spikes. (See Part C, QA/QC for overview and Figure C-1 for explanations of the various types of data.) The following summary statistics (Part D, Chapter 2) must be reported for individual sample matrices/types for each of the following types of quality control data (i.e., field recovery, laboratory recovery, storage stability):

- Means for all samples;
- Standard deviations (σ) for all samples;
- Number of replicates per calculation (n) and reason(s) for excluding any datapoints;
- Coefficients of variation for all samples; and
- 95 percent confidence interval (upper and lower limits) over all fortification levels.

Exclusion of any datapoint from these statistical summaries must be reported and justified (i.e., chain-of-custody problem or extraction/analysis problem). All quality control data should be reported in electronic format and in hard copy. Each individual datapoint must be identified.

I.2.7 Residue Data

Data contained in post-application exposure studies can represent one of two types of residues including: (1) environmental matrix levels such as found in soil or foliar samples, and (2) dosimeter levels such as found in a whole-body dosimeters or filters used for inhalation monitoring.

Typically, environmental matrix data are presented as individual replicate sample results collected at specific intervals after application. All such data should be reported as individual datapoints and not just means at each sampling interval. Residue levels should be presented on a µg/cm^2 basis where appropriate (e.g., foliar dislodgeable residue levels on a double-sided leaf where a single 1-inch diameter disc represents 10 cm^2 of surface area). Soil residue levels should be presented on a ppm basis (i.e., µg/g soil).

Human exposure monitoring data are complex and may take many forms, depending upon the study design. Most investigators will usually opt to use passive dosimetry techniques for monitoring human exposure levels concurrent to the collection of environmental samples. [Note: For this reason, the discussion here will focus on the use of passive dosimetry. See the environmental matrix description in Part B, Chapter 10 for a discussion of biological monitoring data/results.] Typically, passive dosimetry data are presented as three distinct types of results, identified as the following:

- Dermal exposure (nonhand);
- Dermal exposure (hand); and
- Inhalation exposure.

Dermal (nonhand) exposure levels may be presented in a variety of fashions, depending upon the design of the study (i.e., which types of dosimeter are used). If the Durham and Wolfe patch technique is used, all raw data should be presented on a body sample location basis as µg/cm^2. If whole body-dosimetry is used in the study, all data should be reported either as: (1) total µg/sample, or (2) µg/cm^2, where the surface used to calculate the residue level is based on the unit surface areas for representative body parts as presented in Part D, Chapter 2. Dermal (hand) exposure levels should be presented as total µg/sample. Data for hand exposure monitoring samples can be reported for both hands combined or for each individual hand. Additionally, hand exposure results should be reported in a way that represents cumulative exposure over the course of an exposure monitoring interval (e.g., if hand samples were collected prior to lunch and at the end of a work day and if the dermal (nonhand) samples were collected only at the end of an exposure interval).

Inhalation data should to be reported in a slightly different format because of the nature of the monitoring techniques. The following types of data are typically required to calculate inhalation exposure levels:

- Residue levels presented as total residues in a sample (µg/sample);
- Flow rates (Lpm) when personal monitoring pumps are used for sampling (initial, final and mean values); and
- Conversion calculations for passive monitors, if used (e.g., equations for 3M™-type monitors).

I.2.8 Other Critical Considerations

The following issues must be reported in any submission to the Agency:

- Compliance with PR 86-5 (Standard Format for Data Submitted Under FIFRA and Certain Provisions of the FFDCA);
- Compliance with GLPs, specifically protocol amendments and deviations; and
- A statement of adherence to the FIFRA GLP standards.

I.3 EXPOSURE/RISK CALCULATIONS

The required types of calculations/parameters include: (1) residue dissipation kinetics; (2) determination of the proper exposure scenario based on detailed product use and activity pattern data; (3) exposure estimates (potential and internal); (4) relationship between activity, ambient residue levels, and exposure (e.g., transfer coefficients); and (5) the regulatory implications of these calculations (e.g., development of Restricted Entry Intervals and product use restrictions and/or cancellations). See Part D, Chapter 2 - Calculations for a description of the calculations required.

1.4 DISCUSSION AND INTERPRETATION OF RESULTS

This section provides the submitter the opportunity to present a discussion and interpretation of the results. It should include a discussion of all assumptions used in the exposure calculations. Results should be discussed in terms of uncertainty and variability associated with the data. Detailed discussions may be needed for specific factors affecting the exposure estimate. Examples of these types of factors may include regional variations in HVAC system usage, or regional differences in cultural crop practices. Other uncertainties may include those associated with the nature of the population (i.e., based on age, gender, inherent variability, etc.).