CHAPTER 4

PREPARATION OF DATA DOSSIERS FOR THE CONSIDERATION OF THE FAO PANEL OF JMPR

CONTENTS

4.1 ORGANIZATION OF THE DOSSIER

Before a pesticide can be considered for JMPR evaluation it must already be available for use as a commercial product, which means that scientific studies have been prepared and then evaluated in national registration systems. Such studies are generally adequate for JMPR purposes and dossiers of reports prepared for modern registration systems are generally suitable for JMPR. However, JMPR does not review some topics, e.g., efficacy, some environmental fate aspects and ecotoxicology, and they need not be included in the dossier submitted to JMPR. If submitted, these studies will not be referenced or summarised in the Monograph.

The dossier to be submitted to the FAO Panel of JMPR should be arranged within the following topics. It comprises the technical reports provided in support of the working paper or submission summary (see below).

0. Data directory (see below, also Appendix VII)
1. Background information
2. Metabolism and environmental fate
3. Residue analysis
4. Use patterns
5. Residues resulting from supervised trials on crops
6. Fate of residues in storage and processing
7. Residues in animal commodities
8. Residues in food in commerce
9. National residue definitions
10. References, for all studies submitted

A table of contents should be included at the beginning of each volume. Each volume should be clearly labelled as per the example below:

Company name
Date
Common name of the active ingredient
Number of the volume and total number of volumes in the submission
Title of the section

A list of commodities dealt with in that volume (for residue trials, farm animal feeding, processing and storage stability) and a list of animals, crops, soil and water (for metabolism).

Example:

Bayer AG
November 1992
Fenthion

Volume 15 of 18
Section 5 Residues resulting from supervised trials

Citrus fruits
lemons, oranges, tangelos

Pome fruits
apples, pears

4.1.1 Data submission

A hard copy and or electronic copy, based on the reviewer's preference, of the data is to be submitted directly to the reviewer, with an electronic copy provided to the FAO Joint Secretary. If the original data are not available in electronic files, the reports shall first be scanned in pdf formats.

Working papers, summaries of GAP and residue data should be provided in Word format and diagrams of metabolism pathways prepared using a commercial chemical structure drawing program suitable for inclusion as a graphic in the document.

4.2 DATA DIRECTORY

See also Appendix VII, "Standardized format for organizing the data directory (index) of information to be submitted for evaluation."

Manufacturers are required to supply to the FAO Joint Secretary a detailed index or directory of the information to be provided for the residue evaluation by 1 September of the year preceding the scheduled review.

The directory provides an opportunity for data submitters to conduct a brief overview of the data package and identify gaps or omit studies which are not up to current standards and it ensures that an acceptable data package will be available for the consideration of the FAO Panel.

A review of the directory prior to submission of the actual data facilitates planning for the JMPR and helps ensure an equitable distribution of work among the Panel members. A comprehensive data directory simplifies the process of finding relevant sections or studies during the evaluation, particularly in a large submission. In addition, these directories provide a permanent record of the data submitted.

It is not possible for the FAO Joint Secretary to determine from the directory the acceptability of residue data in relation to the use pattern, the availability of critical supporting studies or the monograph. This initially remains the responsibility of the data submitter and ultimately the task of the FAO Panel.

The detailed reports submitted to the FAO Panel in support of the monograph must be organised according to the standardised format of the directory (Appendix VII). Reports or submissions developed for national regulatory authorities may still be collated according to this format.

An electronic copy of the data directory should be supplied in Word format to allow document searches and for incorporation of the references into the Evaluation.

The JMPR manual for FAO Panel members (Appendix X) may also be useful to those preparing data submissions for review.

4.3 WORKING PAPER OR MONOGRAPH

Manufacturers are required to submit a working paper or monograph in MS Word format summarising the results of the trials and the conclusions drawn from them, together with copies of original reports, by 30 November of the year before the scheduled review.

The working paper should, where appropriate, relate the residue data to the residue definition, analytical methods, GAP information, dose levels in animal studies etc., and clearly demonstrate the basis for a proposed MRL. The sub-sections describing supervised trials should follow the sequence of the Codex Commodity Classification and conclude with an evaluation of the information provided.

In the case of submissions provided in support of a new or revised MRL, the evaluation may be limited to a brief discussion of the available residue data and GAP information. In the latter case, new critical supporting studies are valuable information and should be submitted. The re-submission of previously evaluated studies is not necessary, but the relevant studies should be referenced.

The preparation of a draft working paper is expected to facilitate the evaluation of the data by the reviewer and the overall operation of the Panel. It is not intended as a substitute for the FAO Panel review of the individual study reports.

Reports (in English) prepared for submission to authorities, for example in USA and Europe, are likely to be considered generally acceptable. Where such reports are not in the format specified below, a directory must be provided which permits the reviewer ready access to the individual technical reports. There may also be the need for additions to such submissions, for example:

- commodity descriptions in Codex terms,
- summaries of good agricultural practices,
- summaries of residue data from supervised trials,
- summary of residue definitions.

The data and information required for JMPR evaluation and the formats recommended for preparing the summary information are described in detail in Chapter 3 "*Data and information required for JMPR evaluations*". The information from the individual studies should be organised according to the suggested subheadings in the directory with an evaluation of the available data in each subsection. Under the various subheadings, explain any trial details relevant to the assessment of the data that might be considered to influence the residues or the validity of the trials.

Include schematic diagrams of metabolism pathways in electronic form.

Processing studies should be grouped according to the commodity or substrate of interest. Summarise the data in tabular format. Such tables should be set out carefully so that it is absolutely clear which sample is derived from which product in the processing phase. The scale of the processing by the weight of commodity processed should be indicated. The review of each study should describe the field treatments and state the application rate in the study.

Include flow diagrams to explain any complex commercial processes.

4.3.1 Utilisation of national evaluations

The evaluations conducted by national and regional authorities are useful to JMPR in the preparation of compound evaluations.

With the dossier submitted to the JMPR, submitters should include copies of available evaluations performed by regional or national authorities. This recommendation in no manner negates the requirement for the manufacturer(s) to provide *all* relevant original studies, as these will continue to be the primary source.