APPENDIX 7

FORMAT FOR THE LISTING OF TEST AND STUDY REPORTS AND OTHER DOCUMENTATION EVALUATED

(Annex A - list of information tests and studies evaluated)

1 As indicated in paragraph 4.5.1, the listing should cover each separate chapter specified for the preparation of the evaluation and assessment to be included as Annex A of the Monograph. It should include a listing of all test and study reports, test guidelines, and published papers submitted in support of the application (Documents J, K and L and where relevant I) and other relevant information available to, or brought to the attention of, the regulatory State.

2 Within chapters, references should be listed alphabetically by first author. Where there is more than one reference for a particular author (first author), the references concerned should be listed in chronological order - the most recent being listed last. In cases where for a particular author, more than one reference is listed for any one year, the references should be distinguished by inserting letters after the year *i.e.* a, b, c, *etc.*, as appropriate.

3 For each reference, the following indications should be provided -

(i) the data point addressed (number), the reference number and the year of the report or publication;

(ii) for each test and study report, test guidelines, and published paper, its title, source, company and report number;

(iii) whether it is published or unpublished;

(iv) whether, or not, it was conducted in compliance with the principles of GLP or the principles of GEP, as appropriate;

(v) the owner of the test or study concerned; and

(vi) whether or not protection in accordance with the rules or provisions in place in the country to which application is made, is claimed.

4 References which relate to more than one chapter should be listed in each relevant chapter. Where, for existing active substances, documentation is submitted by more than one company, the reference list should reflect all the test and study reports, test guidelines, and published papers submitted. Those references not submitted by applicants, but which are available to, or are brought to the attention of the regulatory authority, should be included. Within the listing for each chapter, the references relevant to the active substance should be presented first and be followed by the references relevant to the formulation. Where documentation relating to more than one formulation is submitted in support of an application, care must be taken to indicate the preparation to which particular test and study reports, test guidelines, and published papers relate.

5 The reference lists that follow are intended to be illustrative of the required approach and relate to a fictitious compound, *Microbial Pest Control Agent Beauvaria wendiensis* strain XYZ1.

MPCA – *Beauvaria wendiensis* strain XYZ1Name of the Regulatory AuthorityMonth & Year List Compiled

Section A.6, Toxicology

Author(s)	OECD data point number / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner

Microbial Pest Control Agent Data and Information

Elberg A	IIM 5.3.7.1/01	2001	*B. wendiensis* strain XYZ1/ study for Primary Dermal Irritation. Vatrobe, Inc. Report No: V470 GLP, Unpublished	N	VAT
Evans R Snowiffle J	IIM 5.3.2	1989	*B. wendiensis* strain XYZ1/ study for acute oral infectivity and pathogenicity. Bekab, Inc. Report No: BK 34569 Vatrobe, Inc. Report No: V460 GLP, Unpublished	N	BEK
Greats W.	IIM 5.1	2002	Summary of the infectivity/pathogenicity potential for *B. wendiensis* strain XYZ1 in humans based on study results and taxonomic relationship to known pathogens. Vatrobe, Inc. Report No: V250 Not GLP, Unpublished	N	VAT
Greats W.	IIM 5.2	2002	Occupational health surveillance report on workers during production of *B. wendiensis* strain XYZ1 Vatrobe, Inc. Report No: V252 Not GLP, Unpublished	N	VAT
Greats W.	IIM 5.3.7.1/02	2002	Justification for non-submission of data for 28-day inhalation toxicity (rodents) Vatrobe, Inc. Report No: V351 Not GLP, Unpublished	N	VAT
Greats W	IIM 5.3.5	2002	Discussion of potential for genotoxic toxin production. Vatrobe, Inc. Report No: V253 Not GLP, Unpublished	N	VAT
Greats W	IIM 5.2.5	2002	Proposed first aid measures and medical treatment. Vatrobe, Inc. Report No: V254 Not GLP, Unpublished	N	VAT
Greats W	IIM 5.6	2002	Summary of mammalian toxicity and overall evaluation Vatrobe, Inc. Report No: V259 Not GLP, Unpublished	N	VAT

MPCA – *Beauvaria wendiensis* strain XYZ1Name of the Regulatory AuthorityMonth & Year List Compiled

Section A.6, Toxicology

Author(s)	OECD data point number / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Kovac K Evans R Snowiffle J	IIM 5.3.2	2000	*B. wendiensis* strain XYZ1/ study for acute oral infectivity and toxicity in rats. Vatrobe, Inc. Report No: V459 GLP, Unpublished	Y [7]	VAT
Kovac K Jones JR Evans R	IIM 5.3.3	2001	*B. wendiensis* strain XYZ1/ study for acute intratracheal/inhalation infectivity and toxicity. Vatrobe, Inc. Report No: V462 GLP, Unpublished	Y [7]	VAT
Kovac K Jones JR Evans R	IIM 5.3.4	2001	*B. wendiensis* strain XYZ1/ study for acute intravenous/intra peritoneal infectivity. Vatrobe, Inc. Report No: V467 GLP, Unpublished	Y[7]	VAT
Parmon D Helpar G Washal B	IIM 5.5/ 01	1962a	Effects on Rodents of *Beauvaria* isolates. J. Bacteriol. 1962 2:45-49. Not GLP, Published	N	
Parmon D Helpar G Washal B	IIM 5.5/ 02	1962b	Pathogenicity and Toxicity of *Beauvaria* species. Microbiol. Rev. 1962 7:22-24. Not GLP, Published	N	

[7] protection for 5 years claimed from date of registration - the study report has not previously been submitted in support of an application for registration