

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 - (iii) whether it is published or unpublished;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.

te to a fictitious compound,

Microbial Pest Control Agent Beauvaria wendensis strain XYZ1.

