

COMMISSION
OF THE
EUROPEAN COMMUNITIES

1607/VI/97 rev.2
10/6/1999

Directorate-General for Agriculture

VI B II-1

Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market

FOREWORD

Directive 91/414/EEC concerning the placing of plant protection products on the market provides in Article 6 (2) and (3) and Article 13 (1) that a dossier satisfying the requirements of Annexes II and III has to be submitted by applicants.

These guidelines are intended to provide guidance to applicants on data concerning residues as required in Annex II part A section 6 and Annex III, part A section 8 of Directive 91/414/EEC (as amended by Directive 96/68/EC) for the authorization of a plant protection product. Indeed the introduction of Annex II, part A, section 6 provides in point (iii) that studies should be performed according to the guidance available on regulatory testing procedures for residues of plant protection products in food. The current document intends to give this guidance.

It has been conceived as an opinion of the Commission Services and elaborated in co-operation with the Member States. It does not however intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State in the implementation of provisions concerned, nor any case law by the European Court of Justice.

Note: The document is currently divided in nine individual documents:

- 7028/VI/95 rev.3: Appendix A - Metabolism and distribution in plants
- 7029/VI/95 rev.5: Appendix B - General recommendations for the design, preparation and realization of residue trials
- 7524/VI/95 rev.2: Appendix C - Testing of plant protection products in rotational crops
- 7525/VI/95 rev.2: Appendix D - Comparability, extrapolation, group tolerances and data requirements
- 7035/VI/95 rev.5: Appendix E - Processing studies
- 7030/VI/95 rev.3: Appendix F - Metabolism and distribution in domestic animals
- 7031/VI/95 rev.4: Appendix G - Livestock feeding studies
- 7032/VI/95 rev.5: Appendix H - Storage stability of residue samples
- 7039/VI/95 : Appendix I - Calculation of Maximum Residue Levels and Safety Intervals e.g. Pre-harvest Intervals.

The Appendices C, D and I are still under discussion and will be amended as soon as possible. The other Appendices reflect the current consensus but might have to be amended when more experience is available.