

## ANNEX IIIB

### ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.
2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.
3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

#### XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies
  - 1.1. If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin
  - 1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required for the biocidal product

#### XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Where relevant all the information required in Annex IIIA, Section XII
2. Testing for distribution and dissipation in the following:
  - (a) Soil
  - (b) Water
  - (c) Air

Test requirements 1 and 2 above are applicable only to ecotoxicologically relevant components of the biocidal product

#### XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds
  - 1.1. Acute oral toxicity, if not already done in accordance with Annex IIB, Section VII
2. Effects on aquatic organisms
  - 2.1. In case of application on, in, or near to surface waters

- 2.1.1. Particular studies with fish and other aquatic organisms
- 2.1.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites
- 2.1.3. The studies referred to in Annex IIIA, Section XIII, parts 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product
- 2.2. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions
- 3. Effects on other non-target organisms
  - 3.1. Toxicity to terrestrial vertebrates other than birds
  - 3.2. Acute toxicity to honeybees
  - 3.3. Effects on beneficial arthropods other than bees
  - 3.4. Effects on earthworms and other soil non-target macro-organisms, believed to be at risk
  - 3.5. Effects on soil non-target micro-organisms
  - 3.6. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
  - 3.7. If the biocidal product is in the form of bait or granules
    - 3.7.1. Supervised trials to assess risks to non-target organisms under field conditions
    - 3.7.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
- 4. Summary and evaluation of parts 1, 2, and 3