ANNEX IIIA

ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES CHEMICAL SUBSTANCES

1. Dossiers on active substances 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.

III. PHYSICAL AND CHEMICAL PROPERTIES

1. Solubility in organic solvents, including effect of temperature on solubility ([1])

2. Stability in organic solvents used in biocidal products and identity of relevant breakdown products ([2])

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

1. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant

VI. TOXICOLOGICAL AND METABOLIC STUDIES

1. Neurotoxicity study

If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another test species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected a test for response to reactivating agents should be considered

2. Toxic effects on livestock and pets

3. Studies related to the exposure of the active substance to humans

4. Food and feedingstuffs

If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Section XI, part 1 shall be required

5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section XI, part 2 shall be required

6. If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required

7. Mechanistic study — any studies necessary to clarify effects reported in toxicity studies

VII. ECOTOXICOLOGICAL STUDIES

1. Acute toxicity test on one other, non-aquatic, non-target organism

2. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Sections XII and XIII shall be required

3. If the result of the test in paragraph 7.6.1.2 of Annex IIA is negative and if the likely route of disposal of the active substance is by sewage treatment then the test described in Section XIII, part 4.1 shall be required

4. Any other biodegradability tests that are relevant from the results in paragraphs 7.6.1.1 and 7.6.1.2 of Annex IIA

5. Phototransformation in air (estimation method), including identification of breakdown products ([1])

6. If the results from paragraphs 7.6.1.2 in Annex IIA or from paragraph 4, above, indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Section XII, part 1.1, part 2.1 and, where appropriate, part 3 shall be required

VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

1. Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances[(1)]

Notes

([1]) These data must be submitted for the purified active substance of stated specification.

([2]) These data must be submitted for the active substance of stated specification.

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies

1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedstuffs

1.2. Behaviour of the residue of the active substance, its degradation products and, where relevant, its metabolites on the treated or contaminated food or feedstuffs including the kinetics of disappearance

1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health

1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means

1.5. If residues of the active substance 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

1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance

1.7. Proposed acceptable residues and the justification of their acceptability

1.8. Any other available information that is relevant

1.9. Summary and evaluation of data submitted under 1.1 to 1.8

2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Fate and behaviour in soil

1.1. Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products

1.3. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

1.4. Extent and nature of bound residues

2. Fate and behaviour in water

2.1. Rate and route of degradation in aquatic systems (as far as is not covered by Annex IIA, paragraph 7.6) including identification of metabolites and degradation products

2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products

3. Fate and behaviour in air

If the active substance is to be used in preparations for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant, then the rate and route of degradation in air shall be determined as far as is not covered by Section VII, part 5

4. Summary and evaluation of parts 1, 2 and 3

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds

1.1. Acute oral toxicity — this need not be done if an avian species was selected for study in Section VII, part 1

1.2. Short-term toxicity — eight-day dietary study in at least one species (other than chickens)

1.3. Effects on reproduction

2. Effects on aquatic organisms

2.1. Prolonged toxicity to an appropriate species of fish

2.2. Effects on reproduction and growth rate on an appropriate species of fish

2.3. Bioaccumulation in an appropriate species of fish

2.4. *Daphnia magna* reproduction and growth rate

3. Effects on other non-target organisms

3.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. A different test organism shall be chosen from that used in Section VII, part 1

3.2. Toxicity to earthworms and to other soil non-target macro-organisms

3.3. Effects on soil non-target micro-organisms

3.4. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

4. Other effects

4.1. Activated sludge respiration inhibition test

5. Summary and evaluation of parts 1, 2, 3 and 4

(**1**) OJ L 20, 26.1.1980, p. 43.