

## SCHEDULE 3

Regulation 5

(This Schedule sets out the provisions of Annex VIII to the Directive)  
ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER REGULATION 5

Tests under this Part shall be according to methods recognized and recommended by the competent international bodies where such recommendations exist.

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be indicated.

## LEVEL 1

### *Physico-chemical studies*

Further studies on physico-chemical properties are dependent upon the results of the studies laid down in Annex VII. Such further studies could include for example the development of analytical methods which make it possible to observe and detect a substance or its transformation products and studies on thermal decomposition products.

### *Toxicological studies*

Fertility studies (one species, one generation, male and female, most appropriate route of administration).

If there are equivocal findings in the first generation, study of a second generation is required.

Depending upon the dosing schedule it may be possible in this study to obtain an indication of teratogenicity. A positive indication should be examined in a formal teratology study.

- Teratology study (one species, most appropriate route of administration).
- This study is required if teratogenicity has not been examined in the fertility study.
- Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study in Annex VII or other relevant information demonstrate the need for further appropriate investigation.
- The effects which would indicate the need for such a study could include for example:
  - (a) serious or irreversible lesions;
  - (b) a very low or absence of a “no effect” level;
  - (c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.
- Additional mutagenesis studies and/or screening study(ies) for carcinogenesis as prescribed in the testing strategy described in Annex V. When both tests in the base set are negative, further tests shall be conducted according to the specific properties and the proposed use of the substance.
- When a test or both tests were positive in the base set, a supplementary should include the same or different end points in other in vivo test methods.
- Basic toxicokinetic information.

### *Ecotoxicity studies*

- Prolonged toxicity study with *Daphnia magna* (21 days).
- Tests on higher plants.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- Tests on earthworms.
- Further toxicity studies with fish.
- Tests for species accumulation: one species, preferably fish.
- Supplementary degradation study(ies), if sufficient degradation has not been proved by the studies laid down in Annex VII.
- Further studies on absorption/desorption dependent upon the results of the investigations laid down in Annex VII.

## LEVEL 2

### *Toxicological studies*

The test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:

- Chronic toxicity study.
- Carcinogenicity study.
- Fertility study (e. g. three-generation study): only if an effect on fertility has been established at level 1.
- Developmental toxicity study on perinatal and postnatal effects.
- Teratology study (species not employed in the respective level 1).
- Additional toxicokinetic studies which cover biotransformation, pharmacokinetics.
- Additional tests to investigate organ or system toxicity.

### *Ecotoxicological studies*

- Additional tests for accumulation, degradation, mobility and absorption/desorption.
- Further toxicity studies with fish.
- Toxicity studies with birds.
- Additional toxicity studies with other organisms.