

ECOTOXICITY TESTING METHODS TO BE USED BY THE REACH REGULATION

COUNCIL REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

- (1) Pursuant to Regulation (EC) No 1907/2006, test methods are to be adopted at Community level for the purposes of tests on substances where such tests are required to generate information on intrinsic properties of substances.
- (2) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances laid down, in Annex V, methods for the determination of the physico-chemical properties, toxicity and ecotoxicity of substances and preparations. Annex V to Directive 67/548/EEC has been deleted by Directive 2006/121/EC of the European Parliament and of the Council with effect from 1 June 2008.
- (3) The test methods contained in Annex V to Directive 67/ 548/EEC should be incorporated into this Regulation.
- (4) This Regulation does not exclude the use of other test methods, provided that their use is in accordance with Article 13(3) of Regulation 1907/2006.
- (5) The principles of replacement, reduction and refinement of the use of animals in procedures should be fully taken into account in the design of the test methods, in particular when appropriate validated methods become available to replace, reduce or refine animal testing.
- (6) The provisions of this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006

Article 1: The test methods to be applied for the purposes of Regulation 1907/2006/EC are set out in the Annex to this Regulation.

Article 2: The Commission shall review, where appropriate, the test methods contained in this Regulation with a view to replacing, reducing or refining testing on vertebrate animals.

Article 3: All references to Annex V to Directive 67/548/EEC shall be construed as references to this Regulation.

Article 4: This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 June 2008.

LIST OF METHODS FOR THE DETERMINATION OF ECOTOXICITY

- C.1. Acute toxicity for fish
- C.2. *Daphnia* sp. Acute immobilisation test
- C.3. Algal inhibition test
- C.4. Determination of 'ready' biodegradability
 - Part i. General considerations
 - Part ii. Doc die-away test (method C.4-a)
 - Part iii. Modified oecd screening test (method C.4-b)
 - Part iv. Co₂ evolution test (method C.4-c)
 - Part v. Manometric respirometry test (method C.4-d)
 - Part vi. Closed bottle test (method C.4-e)
 - Part vii. M.I.T.I. Test (method C.4-f)
- C.5. Degradation — biochemical oxygen demand
- C.6. Degradation — chemical oxygen demand
- C.7. Degradation — abiotic degradation: hydrolysis as a function of pH
- C.8. Toxicity for earthworms
- C.9. Biodegradation — Zahn-Wellens test
- C.10. Biodegradation — activated sludge simulation tests
- C.11. Biodegradation — activated sludge respiration inhibition
- C.12. Biodegradation — modified SCAS test
- C.13. Bioconcentration: flow-through fish test
- C.14. Fish juvenile growth test
- C.15. Fish, short-term toxicity test on *embryo* and sac-fry stages
- C.16. Honeybees — acute oral toxicity test
- C.17. Honeybees — acute contact toxicity test
- C.18. Adsorption/desorption using a batch equilibrium method
- C.19. Estimation of the adsorption coefficient (K_{oc}) on soil and on sewage sludge Using high performance liquid chromatography (HPLC)
- C.20. *Daphnia magna* reproduction test
- C.21. Soil microorganisms: nitrogen transformation test
- C.22. Soil microorganisms: carbon transformation test
- C.23. Aerobic and anaerobic transformation in soil
- C.24. Aerobic and anaerobic transformation in aquatic sediment systems