



## Science and Research Projects

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### An Assessment of Regulatory Testing Strategies and Methods for Characterising the Ecotoxicological Hazards of Nanomaterials - CB01097

#### Description

Objectives:

There are five main objectives within this project:

- 1) To succinctly describe the current test strategies and associated methods used within current chemicals regulatory ecotoxicological (toxicity and bioaccumulation) assessment.
- 2) To critically review those studies that have characterised the hazard of nanomaterials, summarising and appraising key issues and challenges arising from these.
- 3) To use this information to identify which elements of test strategies and associated methods for hazard assessment are not fit for purpose, giving reasons.
- 4) To propose pragmatic variants on current tests based on the information gathered.
- 5) To propose an experimental programme to empirically test variants on the standard methodologies.

The successful applicant will:

Task 1-Succinctly describe the current and imminent key regulatory tests for hazard assessment of chemicals. (e.g. the Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market; the base set within Annex VIIA of the Notification of New Substances Regulations (NONS): <http://www.hse.gov.uk/nons/nons8a.htm> and REACH base sets). The purpose is to identify specific areas of chemicals legislation that characterise hazard which may apply to nanomaterials, and succinctly describe the elements of the strategies and tests, with links to appropriate sources of information.

Task 2-Review those studies that have assessed hazard of nanomaterials, further discussing with researchers their experiences of working with these materials. The output of this task should be a synthesis of key observations and critical issues that apply to nanomaterials in the specific context of regulatory test methods. It should build on and add value to the work undertaken by SCENIHR, ILSI and others (e.g. ECETOC).

Task 3-Building on Tasks 1 and 2, identify which elements of specific testing strategies and methods for hazard (toxicity and bioaccumulation) characterisation are not fit for purpose when considering nanomaterials, with concise reasons as to why this should be the case, citing clear lines of evidence in each case.

Task 4-Propose variants on current test methods outlined in Task 1 that address the issues identified in Task 3, based on the assessment undertaken within Task 2. Where specific elements have been amended, removed or new elements added this should be clearly demarcated. Additions and amendments should be pragmatic and reasonable i.e. with an understanding and appreciation of cost, feasibility and the 3Rs approach (Reduction, Refinement and Replacement of animals used in experimentation). Particular attention should be given to the latter point in order to consider all approaches that will lead to the minimisation of animal use in any testing strategy proposed. The development of integrated testing strategies should be considered.

Task 5-Propose an outline experimental approach designed to empirically test the hypothesis that any variants are fit for purpose through investigation, forming the basis for the next phase of work in this area.

Task 6-Present the findings of the work to Defra, other Government Departments and Agencies within NRCG at the discretion of the NRCG chair and revise the final report based on stakeholder feedback.

### Project Documents

- **Final Report** : [An Assessment of Regulatory Testing Strategies and Methods for Characterizing the Ecotoxicological Hazards of Nanomaterials](#) (534k)
- **Final Report** : [An Assessment of Regulatory Testing Strategies and Methods for Characterizing the Ecotoxicological Hazards of Nanomaterials \(Expanded Report\)](#) (973k)

### Related Documents

- **ROAME Document** : [Chemicals and nanotechnologies division \(CN\) research programme](#)

### Time-Scale and Cost

**From:** 2006

**To:** 2007

**Cost:** £24,560

### Contractor / Funded Organisations

[Watts and Crane Associates](#)

### Keywords

[Environmental Protection](#) [Pollution](#) [Chemicals](#)

### Fields of Study and Contacts

[Chemicals and Nanotechnology](#) - [chemicals.strategy@defra.gsi.gov.uk](mailto:chemicals.strategy@defra.gsi.gov.uk)

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