ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on information requirements and chemical safety assessment.

Appendix R7-1 Recommendations for nanomaterials applicable to:

Chapter R7b Endpoint specific guidance

Appendix R7-1 Recommendations for nanomaterials

1. INTRODUCTION TO APPROACHES TAKEN FOR APPENDICES CONCERNING INFORMATION REQUIREMENTS

The three appendices concerning information requirements (appendices to R7a, R7b and R7c) have been developed in order to provide advice to registrants for use when preparing registration dossiers for nanomaterials. The content of the appendices implements the advice provided by the REACH Implementation Project on Nanomaterials 2 (RIP-oN2) on specific aspects of information requirements concerning materials in nano form.

The final report of the RIP-oN2 project contains a large amount of information including within its scope applicability of the methods, research gaps etc. This appendix implements only the agreed outputs (i.e. the recommendations for guidance update on which there was consensus).

In the appendices only information on the endpoints for which a recommendation has been made are included. In the absence of any specific recommendation, either because the endpoint is not relevant for nanomaterials (e.g. flash point or surface tension), or the guidance already provided is considered to be equally applicable to nanomaterials or because more research is needed before developing advice, no additional information for the endpoint has been included in this appendix.

Note that new parameters or endpoints (such as ventilation rate, or gill pathologies) have been proposed only when these were explicitly recommended to be included as guidance updates in RIP-oN2.

For further information (e.g. recommended further research & development or reasoning for the advice provided for guidance updates, the reader can refer to the final report of RIP-oN2. (http://ec.europa.eu/environment/chemicals/nanotech/index.htm).

2. RECOMMENDATIONS FOR ECOTOXICOLOGICAL ENDPOINTS ARISING FROM RIP-oN 2 for NANOMATERIALS:

2.1. Specific advice for endpoints

The recommendations set out in the OECD Guidance Manual for testing (OECD, 2009) and Preliminary Guidance Notes on Sample Preparation and Dosimetry for nanomaterials (OECD, 2010) need to be taken into consideration, especially with regard to methods of suspension, method of nanomaterials introduction, storage and stability of test material, chemical composition of the test media, characterisation of stock dispersions, characterization of samples (prepared from stock dispersions prior to administration/testing and if possible during and/or at the end of the test.

2.1.1. Aquatic pelagic toxicity

When considering testing data on aquatic pelagic toxicity (Section 7.8.4.1), it should be noted that the provision of data on the following parameters (as part of an ensemble of data on additional relevant endpoints considered by the registrant to be of value) is recommended:

- fish ventilation rate,
- fish gill pathologies,
- fish mucus secretion
- fish brain pathology,
- animal behaviour, and
- activity levels of relevant antioxidant enzymes such as catalase (CAT), superoxide dismutase (SOD), glutathione peroxidase (GPX), and glutathione-S-transferase (GST).

Nevertheless, as a thorough understanding of the relevance and impact on the ecosystem and population of such parameters in view of the regulatory risk assessment is missing, their relevance for overall ecotoxicity assessment remain supportive until further research would indicate otherwise.

2.1.2. Toxicity for sediments organisms

Situations when equilibrium partitioning method (EPM) can be applied in estimating toxicity to sediment organisms are presented in Section R. 7.8.9.1 and Section R.7.8.10.1 covering use Non –testing data on toxicity to sediment organisms. Regarding nanomaterials, estimates based on results from "equilibrium partitioning methods" are limited to the distribution of a substance in molecular form. However, substances may also be distributed in the environment as particles (caused by abrasion/weathering of anthropogenic materials) and hence extrapolation based on partitioning may not be relevant. In such a case the partitioning method may underestimate exposure of soil and sediment environments and overestimate the exposure of water. If the particle size is small also air distribution may occur.

There are no estimation methods available for particle distribution so this has to be dealt with on a case-by-case basis. With regard to nanomaterials, the recommendations set out in the OECD Guidance Manual for testing (OECD, 2009) and Preliminary Guidance Notes on Sample Preparation and Dosimetry for nanomaterials (OECD, 2010) need to be taken into consideration, especially in regard to methods of suspension, method of nanomaterials introduction, storage and stability of test material, chemical composition of the test media, characterisation of stock dispersions, as well as characterization of samples (prepared from stock dispersions) prior to administration/testing and possibly during and at least at the end of the test.

2.1.3. Degradation / Biodegradation

Pre-requisite for biodegradation is that the test material is based on organic carbon chemistry (for bulk chemicals as well as for nanomaterials). Majority of the OECD test guidelines are applicable. However, biodegradability assessment may need to be adapted to the particulate nature of nanomaterials dispersed in water or the test specific test media.

Concerning information on degradation/biodegradation (Section R.7.9.3) it should be noted that the OECD biodegradability test methods have been developed and validated principally for assessment of organic compounds whereas many nanomaterials are principally inorganic and even carbon-based nanomaterials arguably tend to be of an inorganic nature. However, surface coating and functionalizations might be organic and consist of biodegradable materials. (Bio)degradability methods measuring carbon dioxide production or oxygen uptake are applicable, but they require large amounts of test material. If several conclusive aerobic degradation tests indicate very low or negligible degradation, then other aerobic degradation

tests will most likely also be negative and it may be useless to proceed with additional tests. It may be better to decide to skip the more elaborate test, and conclude that the substance is not biodegradable (OECD, 2010).

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