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Nanotechnologies — Compilation and description of toxicological screening methods for manufactured nanomaterials

Nanotechnologies — Compilation et description des méthodes de criblage toxicologiques pour les nanomatériaux manufacturés

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 229, *Nanotechnologies*.

Introduction

This Technical Report provides a compilation of methods intended to aid the process of toxicological screening of engineered and manufactured nanomaterials prior to full-scale toxicological testing, analysis, and risk assessment. Toxicological screening methods focus on providing information and tools that can be used in decision-making processes. For instance, this Technical Report provides information on methods that can be used to screen nanomaterials in order to determine whether to continue development of a nanomaterial itself and/or a product containing a nanomaterial; determine whether to take on the cost of performing the remaining tiers within a complete tiered-testing strategy; or determine whether appropriate controls are in place to continue nanomaterial research in the laboratory.

This Technical Report is not intended to supplant or compete with any existing regulatory requirements regarding nanomaterial testing, use, and disposal, nor does it provide a list of validated tests for this purpose.

The information provided is consistent with other International Standards. For example, its sister document 'Compilation and Description of Sample Preparation and Dosing Methods for Manufactured NMs' is developed in concert and discusses methods used to prepare samples in various relevant media for toxicological studies. ISO 10993-18[1] specifically addresses the evaluation of the chemical characterization of materials used in medical devices, ISO 14971[2] points out that a toxicological risk analysis should take into account the chemical nature of the materials, and ISO/TR 13014[3] addresses issues pertaining to the materials themselves. ISO/TR 13121[4] describes a process for identifying, evaluating, and communicating the potential risks of manufactured nanomaterials and provides guidance on tiered nanomaterial toxicity testing.