TECHNICAL REPORT

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Nanotechnologies — Nanomaterial risk evaluation

Nanotechnologies — Évaluation des risques associés aux nanomatériaux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 13121 was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

Introduction

This Technical Report is intended for use in all countries, regardless of whether they have legal or regulatory schemes that address manufactured nanomaterials.

This Technical Report might be useful to those who believe that legal compliance alone is not sufficient for adequate product stewardship or risk management. Organizations should be aware of the regulatory requirements applicable to nanomaterials (and materials generally), and that implementing the process described in this Technical Report does not necessarily mean that the organization will be in compliance with all applicable legal requirements. This Technical Report is not a legal or regulatory compliance guidance document aimed at satisfying the specific legal or regulatory requirements of any particular jurisdiction. Such guidance should be sought from the appropriate regulatory authorities.

This Technical Report is intended primarily for organizations that manufacture or process nanomaterials, or manufacture, process or distribute products that contain manufactured nanomaterials. However, governmental authorities, professionals, and members of the public might also find this information useful.

NOTE This Technical Report is based on the Nano-Risk Framework, an approach created by the Environmental Defense Fund and DuPont. For further details, see http://www.nanoriskframework.org.

Nanotechnologies — Nanomaterial risk evaluation

1 Scope

This Technical Report describes a process for identifying, evaluating, addressing, making decisions about, and communicating the potential risks of developing and using manufactured nanomaterials, in order to protect the health and safety of the public, consumers, workers and the environment.

While the overall product stewardship and risk management process set forth in this Technical Report is not unique to nanomaterials, it supplements recognized approaches by providing, where possible, a focus on information and issues specific to nanotechnologies. It offers guidance on the information needed to make sound risk evaluations and risk management decisions, as well as how to manage in the face of incomplete or uncertain information by using reasonable assumptions and appropriate risk management practices. Further, it includes methods to update assumptions, decisions, and practices as new information becomes available, and on how to communicate information and decisions to stakeholders.

This Technical Report suggests methods organizations can use to be transparent and accountable in how they manage nanomaterials. To that end, it describes a process of organizing, documenting, and communicating what information organizations have about nanomaterials. This includes acknowledging where information is incomplete, explaining how information gaps were addressed, and explaining the rationale behind the organization's risk management decisions and actions.

2 Symbols and abbreviated terms

ADME: Absorption, distribution, metabolism, and excretion

AIChE: American Institute of Chemical Engineers

BAF: Bioaccumulation factor

BCF: Bioconcentration factor

CAS: Chemical Abstract Service

CBI: Confidential business information

CNT: Carbon nanotube

COSHH: Control of Substances Hazardous to Health

CVD: Chemical vapour deposition

DEFRA: U.K. Department for Environment Food and Rural Affairs

EEC: European Economic Community

EHS: Environmental health and safety

EPA: U.S. Environmental Protection Agency

