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Nanotechnologies — Nanomaterial risk evaluation

Nanotechnologies — Évaluation des risques associés aux nanomatériaux

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Foreword

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HPV: High production volume

HSE: U.K. Health and Safety Executive

ILSI: International Life Sciences Institute

ISO: International Organization for Standardization

IUR: Inventory Update Rule

LCA: Lifecycle assessment

LOAEL: Lowest observed adverse effect level

NAICS: North American Industrial Classification System

NGO: Non-governmental organization

NIOSH: U.S. National Institute for Occupational Safety and Health

NCI-NCL: U.S. National Cancer Institute's Nanotechnology Characterization Laboratory

nm: Nanometer

NNI: U.S. National Nanotechnology Initiative

NOM: Natural organic matter

NPPTAC: U.S. National Pollution Prevention and Toxics Advisory Committee

NTP: U.S. National Toxicology Program

OECD: Organization for Economic Co-operation and Development

OPPTS: U.S. EPA Office of Pollution, Prevention, and Toxic Substances

OSHA: U.S. Occupational Safety and Health Administration

R&D: Research and development

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (EU)

ROS: Reactive oxygen species

SETAC: Society for Environmental Toxicology and Chemistry

SIDS: Screening information data set

SME: Small/medium enterprise

TiO_2: Titanium dioxide

TSCA: U.S. Toxic Substances Control Act

WHO: World Health Organization

3 Summary of the process described in this Technical Report

This Technical Report focuses on manufactured nanomaterials that might exhibit novel properties and consist of particles or physically discrete entities that, in their primary, non-aggregated form, are typically at or below 100 nanometers (nm) in one dimension (e.g. nanoplates), two dimensions (e.g. nanofibres), or three dimensions (e.g. nanoparticles). This process is focused primarily on manufactured nanomaterials as they are used in industrial, chemical, manufacturing, and consumer applications, and on the potential risks associated with releases of nanomaterials at some point in their lifecycles. Where a product, process or material contains manufactured nanomaterials, it might not be the nanomaterial component that poses the most significant risk. Accordingly, the focus in this Technical Report on nanomaterials is not intended to suggest that risk management be limited to the evaluation of the nanomaterial component of materials or products.

Step 1. Describe materials and applications

The first step is to identify and describe the manufactured nanomaterials being evaluated and their intended uses or functions (including potential benefits). The organization might also identify analogous materials (i.e. similar materials that are not in the nanoscale and applications) that might help address data gaps.

Step 2. Material profiles

The second step describes a process to develop three sets of "profiles" of (1) the manufactured nanomaterial's physical and chemical properties; (2) inherent environmental, health and safety hazards, and (3) potential human and environmental exposures throughout the nanomaterial's lifecycle. All three profiles work together; for example, exposure information might suggest which hazards are most important to investigate, or vice versa. Similarly, the nanomaterial's properties might suggest which hazard or exposure scenarios are most likely. The profiles of the nanomaterial's hazards and exposures might also include information about the material's potential to reduce hazards or exposures in comparison with the materials they are intended to replace.

The process of developing these profiles should also include identifying and prioritizing data gaps, and deciding how to address such gaps (e.g. by collecting additional data or, in the place of the missing data, using "reasonable worst case assumptions" or values).

Step 3. Evaluate risks

In this step, the information from the profiles is evaluated to identify and characterize the nature and magnitude of the risks (i.e. combination of hazards and exposure) presented by particular manufactured nanomaterials and their anticipated applications.

Step 4. Assess risk management options

Here, the organization evaluates how to manage the risks identified in Step 3 and recommends a course of action. Options might include materials substitution (e.g. using a safer material), product or process modifications, engineering controls, protective equipment, and risk communication.

Step 5. Decide, document, and act

In this step, appropriate to the product's stage of development, the organization decides whether or in what capacity to continue development and production of the nanomaterial (or the process or product using the nanomaterial). The organization documents those decisions and their rationale, and might share appropriate information with relevant stakeholders, both internal and external. The organization might decide that further information is needed and take action to gather it.

Step 6. Review and adapt

Through regularly scheduled reviews, as well as reviews triggered by specific events, the organization might update the risk evaluation, ensure that risk management systems are working as expected, and revise or improve those systems in response to new information (e.g. new hazard data) or new conditions (such as new or altered exposure patterns).

Implementing the process

This process is intended to be implemented flexibly, and does not suggest a “one-size-fits-all” approach. Different organizations, depending on their size and structure, and the legal jurisdictions in which they operate, might have different ways of implementing this process or parts of this process. How it is implemented will depend in part on the organization's position in a nanomaterial's lifecycle. For example, organizations that develop and manufacture nanomaterials for sale as primary products in diverse applications might adopt a broader perspective than organizations that purchase specific nanomaterials for a narrow set of applications. Cooperation and timely information exchange between nanomaterials' suppliers and their customers will be important to effective risk identification and management.

Implementation will be influenced by the nature and degree of regulation of manufactured nanomaterials. While implementing this process does not necessarily ensure compliance with applicable laws, organizations should be aware of and comply with applicable legal requirements, and understand that such requirements might be frequently changing as nanotechnologies develop.

Organizations are encouraged to integrate the elements of this process into their existing product development, product stewardship or supply-chain management processes, occupational health and safety, or quality management (e.g. ISO 9001) or environmental management (e.g. ISO 14001) systems.

Recognizing that most organizations have limited resources, this process suggests approaches or assumptions that can be used to simplify implementation. For example, organizations might use “reasonable worst case scenarios” (e.g. assume that a material is hazardous and implement appropriate worker protection, risk management or engineering protocols), thus potentially decreasing the need (and cost) for generating new hazard or exposure information. Organizations are also encouraged to use existing information and seek information up and down the supply chain about the nature and intended uses of the nanomaterial(s).

Specific individual or individuals (e.g. a team or committee) in the organization should have the defined responsibility for the implementation of this process. In most cases, the responsible person(s) will be someone who already has responsibility for product development. Equally important is the input and participation from individuals who are involved in technical product development, business development and marketing, manufacturing, and legal compliance, frequently in “cross-functional” teams.

Ideally, the team will include professionals competent (whether by education, experience, or a combination of the two) in risk assessment, toxicology, environmental fate, occupational safety and industrial hygiene. However, many organizations might not have the resources to include such staff. It might be necessary to rely on publicly-available literature, engage appropriate outside experts (e.g. hiring consultants such as industrial hygienists or risk assessors, or partnering with university researchers), or participate in consortia to share resources and expertise (where allowed by applicable laws).

Organizations may also choose to include external stakeholders in some or all of the process of implementing the steps set forth in this Technical Report.

This process may be incorporated into or paired with an organization's management and compliance systems to ensure its execution. That system may be an existing product development or product-stewardship process, quality, environmental or occupational health and safety management system, or a new system. The key point is to ensure that responsible and accountable individuals should see to it that the implementation in fact occurs. Moreover, in keeping with the iterative nature of the process, these individuals should also ensure that it is revisited on a periodic and as-needed basis.

The Output Worksheet (Annex F) is meant to facilitate the collection, evaluation, management, and communication of data. The Worksheet provides a template for organizing all information collected during the process, capturing overall evaluations of that information, and recording management decisions on how to act on it. The Worksheet can also be used as the basis for sharing information and decisions with stakeholders[1)].

1) Case studies using the Nano Risk Framework created by Environmental Defense Fund and DuPont can be found at http://www.nanoriskframework.org.

4 Describe materials and applications

4.1 General

The first step is to describe the manufactured nanomaterial(s) and its intended uses[2]. Accurately describing nanomaterials is important, as changes in composition (e.g. surface coatings) might have a substantial effect on the biological behaviour of the materials. Accurate identification is also essential for comparing research results obtained with the same materials at various locations. This description should be sufficient to guide development of the more detailed profiles of the nanomaterial's properties, and its hazard and exposure potential, at various lifecycle stages such as manufacture, use (including maintenance and servicing) and end-of-life. This description should allow the organization's decision makers and interested stakeholders to become familiar with the material, how it might change over time or in different conditions, and its reasonably foreseeable applications.

Much of the information necessary for this step might already be in the possession of the developer, manufacturer or supplier of the nanomaterial, or be available in the literature. An end user might be able to obtain relevant information from its suppliers or the nanomaterial's developer[3]. The information obtained should be reviewed for accuracy and completeness (which might require the assistance of experts).

The lifecycle of a product system involving nanomaterials encompasses all the processes and activities that occur from initial extraction or creation of the material (or its precursors) from the earth to the point at which any of the nanomaterial's residuals are returned to the environment[4]. Organizations should consider both *established* and *reasonably anticipated* activities or processes to which the nanomaterial might be subject over its lifecycle (either intended or unintended).

A formalized lifecycle assessment (LCA) methodology of nanomaterial product systems is not necessary, nor the associated consideration of all material and energy inputs and outputs that LCA typically entails. Rather, the relevant processes and activities throughout the lifecycle of a nanomaterial (or its predecessor or successor materials) should be identified and evaluated to determine whether they carry the potential for the release of, or exposure to, the nanomaterial or any of its derivatives.

Because knowledge of each application might reside downstream of the primary nanomaterials producer, communication up and down the supply chain is necessary to understand the material's potential uses and end-of-life options.

The lifecycle profile helps identify the different organizations (typically, commercial entities) that might be involved in decisions about nanomaterials. While the material manufacturer typically decides on or influences activities (such as workplace-safety practices) “within its four walls,” such decisions can profoundly affect the options available to the other actors in the supply chain. For instance, a decision to use a toxic heavy metal in a product might ultimately compromise the safety of, or limit the disposal or recycling options for that product at the end of its service life.

Organizations' place in the life cycle will affect the breadth and depth of their analyses. A developer and manufacturer of a nanomaterial intended for a potentially broad range of uses should typically undertake a comprehensive and wide-ranging analysis. On the other hand, an end-user that is planning on purchasing a single nanomaterial for use in a single product aimed at a narrow market might conduct a much more focused analysis.

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2) The development and use of nanomaterials can arise in the context of the creation of new products, or the enhancement of or modifications to existing products. Accordingly, the process described in this Technical Report is not limited to new product development.

3) The expectation that this information will generally already be in the possession of the developers is shared by some regulatory agencies. See: National Pollution Prevention and Toxics Advisory Committee [NPPTAC], A Federal Advisory Committee to the U.S. Environmental Protection Agency. Overview Document on Nanoscale Materials, November 22, 2005; Consultation on a Proposed Voluntary Reporting Scheme for Engineered Nanoscale Materials, United Kingdom Department for Environment Food and Rural Affairs [DEFRA], March 2006.

4) ISO 14040 and ISO 14044 provide detailed guidance on LCA.

4.2 Materials descriptions

The physical and chemical description of the manufactured nanomaterial should include chemical composition (including impurities), surface composition, physical structure, physical form, concentration, size (or surface area) distribution, solubility, and aggregation and agglomeration state. An organization should also identify the nanomaterial's sources and the manufacturing processes in which the organization uses (or plans to use) the nanomaterial, and review the literature on its known relevant uses. More guidance on identifying the physical properties of nanomaterials is provided in Clause 6 of this Technical Report.

4.3 Materials sourcing

Describe the source of the inputs used to manufacture the nanomaterials (if you are a developer or manufacturer) or the source of the nanomaterials (if you are a processor or end-user). This includes transport from points of acquisition to the point of processing or use. This information is relevant for determining whether there is potential exposure to nanomaterials at these stages, or if the specific sources of the starting materials influence the composition, properties, or behaviour of the resulting nanomaterial (e.g. by affecting the extent of impurities). Relevant reference materials[5)] should also be identified, as well as "incumbent materials" that might be replaced by the nanomaterial, and bulk counterparts (that is, larger, non-nanoscale materials with the same chemical composition as the nanomaterial).

4.4 Manufacturing

Three substages, materials manufacture, product fabrication, and packaging, are typically involved in the transformation of source materials into a nanomaterial to be delivered to end-users. The degree of detail and relevance of each of these descriptions will depend in part on the evaluating organization's stage in the life cycle.

1) *Materials Manufacture*. Describe the activities involved in converting a source material into a form that can be used to fabricate a finished product. The production of intermediate chemicals or materials is normally included in this category, as is their transport. For example, carbon nanotubes (CNTs) can be produced by several techniques, including arc discharge, laser ablation, chemical vapour deposition (CVD), or high-pressure carbon monoxide (HiPco), each of which can produce nanomaterials with particular characteristics. Since each process can yield a distinct combination of products, it is important that their associated processes, the differences between them, and the differences between the resulting products, be identified.

2) *Product Fabrication.* Describe the use or processing of manufactured nanomaterials to create a product. That product might be an intermediate or component of a larger product, a product intended for industrial or commercial uses, or a consumer product. For example, purification of CNTs, their incorporation into matrices (e.g. to form a polymer nanocomposite), and their preparation for final or intermediate use (e.g. by means of grinding and smoothing operations), or incorporating nanomaterials into a coating, would all be activities in this substage of the lifecycle profile.

3) *Packaging.* Describe the processes that package an intermediate or finished product. Although these activities might change the location or physical configuration of a product, they do not involve a transformation of materials. Packaging CNT-containing polymer pellets for distribution to automotive-parts producers, for example, or packaging molded parts for distribution to end-product manufacturers (or to retail or repair facilities), would be included in this substage.

4.5 Distribution

Describe the transportation modes (e.g. truck, rail, air, marine) that are used throughout the product or service system to deliver a manufactured nanomaterial(s) (or a product containing the nanomaterial(s)) to users (e.g. industrial, commercial, retail, or direct to consumer, such as through internet sales).

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5) In ISO Guide 30:1992, reference materials are defined as follows: "Material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials."

4.6 Use/reuse/maintenance

Describe the intended or reasonably likely uses of the manufactured nanomaterial(s) (or the product containing the nanomaterial(s)) relevant to the organization conducting the evaluation. The reasonably anticipated conditions of use will differ among industrial, professional or consumer uses. For example, the conditions of use in the pharmaceutical or medical device sectors are likely to be more highly controlled than consumer uses. The description of the use may include the improved product performance characteristics that are anticipated to be related to the use or incorporation of nanomaterial(s) (e.g. improved strength/weight ratio, increased efficiency or efficacy, etc.). The description should also take into account activities such as storage, wear and tear, weathering and other conditions of degradation or failure, maintenance, repair, and replacement.

4.7 End of life/recycle/waste management

This describes what occurs after the product or nanomaterial as served its intended purpose and will enter either a new product system (through reuse or recycling) or its end-of-life (through the waste-management system). Post-use possibilities such as recycling, composting, landfills, disposal through wastewater systems (for example, down-the-drain disposal of a personal care product containing nanomaterials), and incineration, and associated distribution, should be considered. If recycling or re-use is a reasonably anticipated option, consideration should be given to whether the “new” uses will be different from the originally anticipated uses.

4.8 Questions to ask regarding the nanomaterial

The following questions and suggestions should help to guide the creation of the basic descriptions of the nanomaterial and its applications (noting that each question might not be relevant to every organization):

4.8.1 Questions to ask regarding the description of nanomaterials

— What is the stage of development (lab scale, pilot, demonstration, commercial, etc.) of this nanomaterial?

— Briefly describe the source of the nanomaterial. Is it manufactured in-house or purchased?

— If purchased, who produces the nanomaterial?

— How is the nanomaterial manufactured?

— How and in what form is it transported to your facility(ies)?

— Is there a larger-sized, or bulk, version of this nanomaterial in commerce?

— What other nanomaterials exist that are similar to this one?

— How long has this nanomaterial, or a similar nanomaterial, been in commerce?

— What are sources of additional information on this nanomaterial?

4.8.2 Questions to ask regarding the description of applications

— What are the known or intended uses of the nanomaterial based on a literature review?

— What are the expected or intended applications of this nanomaterial, (noting especially differences from the uses of incumbent and non-nanomaterial forms of the material).

— Are these uses new compared to any that are already represented in the literature?

— Why is the material being manufactured and used in the nanoscale range, as opposed to other sizes?

— How will you (and your employees or contractors) be handling, using or processing the nanomaterial?

— How will the nanomaterial be handled when received by downstream processors? By end- users?

— In what form will the nanomaterials be present in final products?

— Will the nanomaterials be agglomerated or bound in a matrix in the final product? If so, describe.

— Will the nanomaterial be used by a large number of downstream users? In what form will it be when it is so used?

— How much of the nanomaterial will be present in the intended products? What types and sizes?

— What volume of nanomaterials will be used on an annual basis?

— What new or different application benefits does this nanomaterial offer compared to existing alternatives for the same application?

— What are the other potential applications of this nanomaterial?

— Are there applications for this nanomaterial that intentionally will not be pursued?

— How will the nanomaterials or products be handled and disposed of, post-use?

5 Profiles of the nanomaterials' properties, hazards and exposures

5.1 General

5.1.1 Introduction

This part of the process includes describing the nanomaterial's physical and chemical properties, its inherent hazards, and the exposures associated with its lifecycle. This introduction provides an overview about the data sets associated with these profiles, and what steps can be taken when one does not have all of the desired data. The accurate and complete identification of the manufactured nanomaterials (see Clause 5) is essential to the accuracy of these profiles.

5.1.2 The use of data sets

“Data sets” have been outlined for each of the three main categories of information -physical/chemical properties, hazard, and exposure potential (see Annexes A, C and E for more detailed information on the data sets). Data sets collect those types of data that are deemed by technical professionals to be necessary for the adequate characterization and use of chemicals[6)]. The data sets serve as a reference point for the type and amount of information that should be addressed by the time of a product's commercial launch, and can be used for screening purposes in early stages of product development.

To the extent that there are national or regional legal requirements applicable to the data that must be developed and submitted if a nanomaterial is to be placed on the market or distributed in commerce, those requirements must be met.

6) Data sets are used in other programs that promote or require hazard-data development for chemicals, such as the screening information data set (SIDS) program of the Organization for Economic Co-operation and Development (OECD). Annex G describes some of the sources from which the data sets in this Technical Report were derived.

The data sets are not meant to represent a comprehensive assessment or full toxicological profile of a given nanomaterial. Rather, they are designed to cover the kinds of data that might be required to provide a reasonable balance between an adequate characterization of properties, hazards, and exposure, and a practical strategy for the development of nanomaterials. The strategies outlined in Annexes A to E represent several current approaches for achieving those goals.

It might not be necessary in every case to generate all of the data called for in the data sets. For example, where data are sufficient to rule out a particular route of exposure, the user will not likely pursue hazard evaluations specific to that route. Similarly, one might elect not to pursue certain elements of the data set, or one might need to develop more information than is called for in the data set, depending on the expected uses of a nanomaterial or its stage of development.

These data sets are expected to be dynamic; that is, they will need to be revised as more information is developed or published on nanomaterials' risks and as other efforts to refine appropriate risk-assessment and risk-management approaches are developed or made public.

5.1.3 Use of default values and assumptions

Developing the data sets will typically begin with a survey of existing literature to obtain the characterization, hazard and exposure data necessary for an adequate assessment of risk. However, there might be “gaps” in the literature such that the data sets cannot be completed. It might not be feasible or appropriate, especially at the early stages of product development, to perform new tests on nanomaterials in order to complete the data sets. In these situations, the literature-based data might nonetheless be sufficient to allow initial decisions to be made based on sound (and documented) expert judgment. Where the literature does not support such judgments, one can use “reasonable worst-case” default values or assumptions in the absence of testing and a complete data set, and before commercialization.

“Reasonable worst-case” default *assumptions* can be useful in the absence of complete data, as they allow a risk characterization or a preliminary assessment to be conducted for estimating, in a reasonable worst case, the risks that a nanomaterial might pose. For example, if no data exist on the fate of a nanomaterial discharged to a sewage treatment plant, one could assume that none or very little of the nanomaterial is degraded and most of it is discharged in effluent. That is, the environment gets the full dose. Such assumptions are sometimes used by regulatory agencies as inputs to exposure models when measured data are unavailable[7]. The more data or information on analogous situations is available, the more one can adjust assumptions from a “reasonable worst case” to less conservative assumptions. The factual and analytical predicates for any such assumptions should be transparently described. Further, reasonable worst case scenarios generally do not include speculative or highly improbably assumptions.

“Reasonable worst-case” default *values* can be derived from several sources, such as data available on analogous bulk toxic materials (i.e. non-nanoscale materials that have the same or similar chemical structure as the subject nanomaterial) or non-manufactured nanoparticles. For example, one could manage a nanomaterial as if it were as toxic as a related toxic bulk material for which the toxicity is well understood[8]. It might also be possible to “bridge” or “read across” from data that exists for a similar material (discussed below). If there are no data on the related bulk materials, reasonable worst-case values might come from assignment to the highest-level tier in an existing classification system. For example, one could manage a nanomaterial as if it possessed characteristics of reproductive toxicity sufficient to classify it as a Category 1 substance (known or presumed human reproductive or developmental toxicant) under the UN's Globally Harmonized System for Classification and Labeling[9].

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7) See, e.g. U.S. EPA's New Chemicals Program homepage, http://www.epa.gov/oppt/newchems/index.htm.

8) The nano-scale form of a bulk material may exhibit different properties and thus different hazards than are present in the bulk material. One should not assume, for example, that the nano-scale form of a non-toxic bulk product will not be toxic.

9) United Nations, Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 2005, http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.