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Evaluation of methods for assessing the release of nanomaterials from commercial, nanomaterial-containing polymer composites

Évaluation des méthodes de détermination d'émission de nanomatériaux par des polymères composites commerciaux, contenant des 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

The use of manufactured nanomaterials (MNM) in consumer products and applications is growing as manufacturers exploit the unique properties of nanomaterials. MNMs are an increasingly common feature of a growing variety of commercial applications and consumer products — from computer chips to golf clubs. So too are concerns over what is or can be released from products containing MNMs, and the risk and potential impacts of exposure to such releases. These unique properties offer significant commercial value, enabling the manufacture of products that that offer novel characteristics. The MNM might be embedded in solids, might be suspended in fluid, or might be bound to the surface of solid products. An understanding of what is released from products containing MNMs is critical to planning and managing safe development and use of those products.

This document aims to contribute to that understanding by providing a guide to the information to be taken into account in determining the methods for identifying and evaluating releases of MNMs from matrices; providing a framework for understanding how these methods and the information they produce can support decision-making; and identifying opportunities for developing standards in this area.

This document provides practical support for decisions related to product development and use through early consideration of the potential for release of MNM and through focus on realistic use scenarios where exposures to the released MNM might occur.

The intended users of this document would include:

— those planning to develop or adapt technical specifications for MNM use in commercial products;

— risk managers, product developers, exposure measurement practitioners or other stakeholders seeking guidance on the availability and utility of methods to measure releases that could occur from uses of specific MNMs in composites;

— methods and instrumentation developers seeking to identify needs of the risk management community;

— those planning basic and applied research programs for measurement and modelling to support decisions around sustainably safe uses of MNMs.

The structured review of the information regarding the selection of MNM measurement methods provided in this document is needed because technologies to produce MNMs, their uses, and MNM measurement methods are often developing at the same time, and the development of measurement methods can in some cases lag behind product development needs. Furthermore, the need to measure particular characteristics of the released MNM might also evolve as greater understanding of what might cause toxicity for a particular kind of MNM is gained. This relationship between emerging measurement methods and emerging information about toxicity makes a structured approach to review of measurement needs even more important, so that data are assembled to support decisions using the most up-to-date and fit-to-purpose measurement methods. Finally, the selection process for choosing a particular MNM-composite for a product should include the consideration of whether the available measurement methods are feasible for the evaluating the conditions of use of that MNM-composite. This consideration is needed because many methods available for research or for controlled conditions in industrial hygiene settings are not useful for realistic measurement needs where consumers might be exposed. In some cases, those methods are too difficult to conduct outside of the laboratory, and in other cases the methods are too labour-intensive to be feasible for routine decision support.

The development of the decision-making framework presented in this document is based in large part on initial analyses that focused on releases from polyamide or epoxy polymers to which multi-wall carbon nanotubes (MWCNT) have been added. Nonetheless, the framework can be used to inform the selection of methods for identifying and evaluating the releases for a wide range of MNMs and types of matrices, as illustrated by the case studies in Annex A. The case studies have been chosen because of the availability of information and methods relevant for actual MNM-polymer composite uses.

Release from polymer nanocomposites can occur through processes such as physical, chemical, or thermal degradation of a polymer matrix, resulting in particles that might include a mixture of free MNM, free polymer, and matrix-bound MNM. This document focuses on the first release to human exposure or to an effluent pathway. While acknowledging that subsequent MNM fate and transport could follow from this initial release, the primary concern of this document is whether and where release of MNMs can occur in the context of consumer or commercial use, and the need to monitor likelihood of human exposure potential. Although other stages of the lifecycle of products containing MNMs are discussed briefly to provide context, subsequent fate and transport events are not addressed in detail.

The ultimate goal is to use the report structure of this document as a foundation for addressing releases of other MNMs from other matrices in subsequent versions of the document.

0.2 Decision-Making Framework

0.2.1 General

In developing the decision-making framework set out in this document two key concepts that have proven useful in addressing the relevant risk management issues in support of decision-making have been applied. The first is "problem formulation"[1]. This describes the purpose and context of the analysis, and the nature of the decision that the analysis aims to support. By making it clear the analysis is being conducted to support a specific decision, this approach helps to ensure the analysis remains focused on methods that have practical application in making that decision. The second key concept is "fit for purpose." In other words, the nature of the analytical approach used should be sufficient for and appropriate to addressing the specific risk management decision. This includes assuring that the depth of analysis - including consideration of the sources and potential magnitude of uncertainty – is consistent with the information needed to support the decision. In the context of this document, this means that feasibility is an important consideration in the choice of analytical methods.

0.2.2 Application of concepts

In applying these concepts to the selection of methods for identifying and evaluating releases of MNMs from matrices, the problem formulation would include an evaluation of the potential for human exposure to the component of the nano-enabled product (NEP) that contains the MNM and the potential for MNM release from that component.

To evaluate the potential for human exposure, an understanding of the product design and the potential use scenarios is required. If, for example, the component containing the MNM is fully encased within a consumer product, or is part of a machine where it is accessible only during maintenance, there are limited opportunities for human exposure as part of the release event. Description of potential use scenarios is also critical for understanding the potential nature of human exposure (e.g. direct dermal contact vs. inhalation of released MNM), as well as relevant conditions of potential wear and aging (e.g. potential and nature of abrasion, temperature, presence or absence of water and UV light).

Together, these elements of the problem formulation can aid in determining which potential release scenarios need to be tested, as well as the nature of the analytical methods needed and, thus, aid in determining whether it is feasible to evaluate the risk of a given choice of product composition without substantial investment in analytical methods development.

0.2.3 Tiered approach

In some situations, a tiered approach — such as those described in Clause 8 — can be useful. For example, if release outside of a confined structure is not expected (e.g. if the MNM is contained within a phone, and release would not result in consumer exposure), an analytical method that simply detects the MNM could be sufficient. In other cases, a qualitative description might be useful to predict the potential for further interactions with other materials, and ultimately the fate and transport of the MNM. Such information could be used, for example, in deciding between alternative designs or products

0.2.4 Quantitative risk assessment presents challenges

Finally, in some cases it could be necessary to quantitatively evaluate the MNM release in order to feed into a quantitative risk assessment. In such cases, it is important to ensure that exposure measurements are made in a way that facilitates integration with hazard data to evaluate risk. Such integration includes evaluating the MNM characteristics with regard to key determinants of toxicity (e.g. degree of aggregation and functionalization), and reporting exposure in relevant dose units. Currently completing an evaluation of this kind presents a significant challenge, as the key determinants of toxicity and appropriate dose units are still being identified in many situations.

0.2.5 Data requirements

As described in this document, key data needs to support a decision related to product development and use include:

— a description of the NEP and where in the product the MNM is found;

— a description of common use scenarios, including frequency of use and relevant populations;

— a description of potential degradation mechanisms that can lead to release under the use scenario(s) of interest;

— a description of the nanomaterial;

— a description of the composite matrix and its resistance to degradation under the use scenario(s) of interest.

Based on this information, the assessor can determine the potential for release (including the release rate) and the likely media into which the release might occur. These parameters in turn inform the nature of sampling and analytic methods that might be needed.

0.3 Document structure and use

After a brief discussion of how the topic of this document relates to Lifecycle analysis, the document addresses the structure of the polymer and the embedded MNM, and how those structures inform measurement methods needs through their effect on the release rate and the form of the release (Clause 5). Clause 6 describes how the relative resilience of the polymer matrix and the embedded MNM inform measurement methods needs through their effect on the nature of the resulting release and proposes a tiered (stepwise) decision framework for deciding if or which transformations at the release point need to be considered. Worked examples applying the decision framework outlined in 6.3 are presented in Annex A. Clause 7 addresses methods for measuring and describing the characteristics of the released material, including sampling methods in various media, methods for sample preparation and analysis, and measurement challenges. Clause 8 addresses remaining gaps and data needs, and briefly reviews several available decision frameworks to support risk managers in determining the information and sampling methods needed to support product design and development decisions.

It is anticipated that the information presented in this document will find application in assisting manufacturers and regulatory agencies to more clearly identify products and scenarios with low consumer exposure potential (e.g. where the MNM is part of a component that is fully encased) and those products and scenarios with higher exposure potential (e.g. the MNM is in continuous contact with human skin or is used under conditions subject to severe weathering). This document is also intended to aid in evaluating — at the product design stage — how variation in adducts, coatings, or MNM composition would affect MNM release rates and measurement needs.

Evaluation of methods for assessing the release of nanomaterials from commercial, nanomaterial-containing polymer composites

1 Scope

This document reviews and evaluates the utility of available methods to assess material released from commercial polymer composites in support of product use and safety decisions, and describes what revised or additional methods are needed. The document is not focused on describing methods per se; rather the goal is to describe information that is appropriate for consideration in the selection of methods to support decision-making.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 80004 (all parts), *Nanotechnologies — Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 80004 (all parts) and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
manufactured nanomaterial
MNM
nanomaterial intentionally produced to have selected properties or composition

[SOURCE: ISO/TS 80004-1:2015, 2.9]

3.2
nanocomposite
solid comprising a mixture of two or more phase-separated materials, one or more being nanophase

Note 1 to entry: Gaseous nanophases are excluded [they are covered by nanoporous material].

Note 2 to entry: Materials with nanoscale phases formed by precipitation alone are not considered to be nanocomposite materials.

[SOURCE: ISO/TS 80004-4:2011, 3.2]

3.3
carbon nanotube
CNT
nanotube composed of carbon

Note 1 to entry: Carbon nanotubes usually consist of curved graphene layers, including single-wall carbon nanotubes and multiwall carbon nanotubes.

[SOURCE: ISO/TS 80004-3:2010, 4.3]

3.4
multi-wall carbon nanotube
MWCNT
carbon nanotube composed of nested, concentric or near-concentric graphene sheets with interlayer distance similar to those of graphite

Note 1 to entry: The structure is normally considered to be many single-wall carbon nanotubes nesting each other, and would be cylindrical for small diameters but tends to have a polygonal cross-section as the diameter increases.

[SOURCE: ISO/TS 80004-3:2010, 4.6]

3.5
lifecycle
consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal

[SOURCE: ISO 14044:2006, 3.1, modified — the term has been modified from "life cycle" to "lifecycle".]

3.6
nano-enabled
exhibiting function or performance only possible with nanotechnology

[SOURCE: ISO/TS 80004-1:2015, 2.15]

3.7
single wall carbon nanotube
SWCNT
carbon nanotube consisting of a single cylindrical graphene layer

Note 1 to entry: The structure can be visualized as a graphene sheet rolled into a cylindrical honeycomb structure.

[SOURCE: ISO/TS 80004-3:2010, 4.4]

3.8
nano-enhanced
exhibiting function or performance intensified or improved by nanotechnology

[SOURCE: ISO/TS 80004-1:2015, 2.16]

3.9
nanoscale
length range approximately from 1 nm to 100 nm

Note 1 to entry: Properties that are not extrapolations from larger sizes are predominantly exhibited in this length range.

[SOURCE: ISO/TS 80004-1:2015, 2.1]

3.10
agglomerate
collection of weakly or medium strongly bound particles where the resulting external surface area is similar to the sum of the surface areas of the individual components

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example van der Waals forces or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed *primary particles*.

[SOURCE: ISO 26824:2013, 1.2]

3.11
graphene oxide
GO
chemically modified graphene prepared by the oxidation of graphite causing extensive oxidative modification of the basal plane

[SOURCE: ISO/TS 80004-13:2017, 3.1.2.13, modified — "and exfoliation" has been deleted.]

3.12
additive
substance added to polymers to improve or modify one or more particles

Note 1 to entry: In a narrow sense, the term additive includes only ingredients added in small amounts; in such cases the term modifier is used for an ingredient added in relatively large amounts.

[SOURCE: ISO 472:1999, Clause 2]

4 Abbreviations

AC article category

AFM atomic force microscopy

AUC analytical ultracentrifugation

CRM certified reference material

ECHA European Chemicals Agency

EC elemental carbon

EM electron microscopy

ERC environmental release category

ES exposure scenario

ESD emissions scenario document

ICP inductively coupled plasma

ICP-MS inductively coupled plasma mass spectrometry

ILS inter-laboratory studies

LCA Lifecycle analysis

LCS lifecycle stage

MCE mixed cellulose ester

NEP nano-enabled or nano-enhanced product

PC polycarbonate

PP polypropylene

PROC process category

PVC polyvinyl chloride

RM reference material

RTM representative test material

SEM scanning electron microscopy

SL service life

SU sector of use

TEM transmission electron microscopy

TO thermal optical

UDS use descriptor system

UV ultraviolet

UV-VIS ultraviolet-visible spectroscopy

WWTP waste water treatment plants

5 Understanding the nano-enabled products

5.1 Pathway analysis for the supply chain

The focus of this document is on release of the MNM in the use phase of the lifecycle, including both consumer and commercial use. However, the design of NEPs needs to consider the potential for MNM release, and ultimately MNM exposure, throughout the lifecycle. Therefore, this clause briefly discusses considerations for the broader NEP lifecycle. The first step in the identification of potential releases along the lifecycle of NEPs is to provide a comprehensive pathway analysis along and beyond their value chain. The basis of this pathway analysis will be the information available about the product and the processes the product passes through during its whole lifecycle. This information might include product composition (nanomaterial and matrix type and composition), production and use volumes for each application, knowledge on fabrication and other lifecycle processes, use profiles (market details) and disposal options. Furthermore, MNM releases in industries strongly depend on the risk mitigation measures applied for waste management and uncontrolled processes.

The estimation of the concentration of chemicals released from products and ending up in the different environmental compartments could be based on the information provided in documents such as OECD Emission Scenario Documents (ESDs). The OECD Working Party on Exposure Assessment develops ESDs in order to reflect conditions on production, use, etc., that are different between countries, and so avoiding duplicative efforts by Member countries and industry. ESDs have been widely used in national and regional contexts. For example, ECHA's guidance document on environmental exposure estimation refers to existing ESDs developed by both OECD and the European Commission. Other OECD member countries have developed their own ESDs and the US EPA has developed several generic scenarios to be used as default release scenarios in risk assessment. The OECD describes an emission scenario as a set of conditions about sources, pathways, production processes, and uses patterns that quantify the emissions (or releases) of a chemical from production, formulation, processing, use and recovery, and disposal into water, air and solid waste. An emission rate is used to quantify releases. Default values are established in a way that reflect an average number for the whole lifecycle considering the emission rate remains constant over time. However, this is not applicable to most of the cases since the rate will decrease over time for most additives.

Furthermore, to support the identification of uses and facilitate effective communication up and down the supply chain, as well as quantification of releases, ECHA has developed a standardized description of uses in the supply chain called the use descriptor system. The UDS was based on six separate descriptors: lifecycle stage, sector of use, process category, product category, article category, and ERC. There are four basic stages in the lifecycle of a substance to which a use can be assigned: manufacture, formulation or repacking, end-use (use in industrial sites, professional use, and consumer use) and (article) SL. A brief description of the product use(s) can be obtained by using these descriptors.

— **Lifecycle stage:** Reflects the stage of the chemical/ nanomaterial in its lifecycle. It is structured in such a way that it indicates the type of organizations using the chemical (or nanomaterial) after its manufacture (e.g. formulators, industrial end users).

— **Sector of use:** Describes in which sector or market area the substance (nanomaterial) is used.

EXAMPLE 1 SU4: manufacture of textiles, leather, fur; SU11: manufacture of rubber products.

— **Process category**: Describes the application techniques or process types defined from an occupational perspective; the PROC, in combination with the operational conditions and risk management measures, is the prime determinant for the level of occupational exposure. It is a required descriptor for worker uses.

EXAMPLE 2 PROC1: Production in closed process without likelihood of exposure or processes with equivalent containment conditions; PROC5: Mixing or blending in batch processes; PROC7: Industrial spraying.

— **Chemical product category**: Describes the types of products in which a substance/ nanomaterial is used. The chemical product category in combination with the operational conditions and risk management measures primarily determines the level of consumer exposure. It is a required descriptor for consumer uses.

EXAMPLE 3 PC9a: Coatings and paints, thinners, paint removers, PC24: Lubricants, greases, release products; PC31: Polishes and wax blends.

— **AC:** Describes the type of article in which the substance/nanomaterial has been processed. The AC is only relevant and used for the lifecycle stage SL.

EXAMPLE 4 AC2b: Other machinery, mechanical appliances, electrical/electronic articles; AC8e: Paper articles: Furniture and furnishings; AC13a: Plastic articles: large surface area articles.

— **ERC:** Describes the broad conditions of use from an environmental perspective, based on those characteristics that give a first indication of the potential release of the substance to the environment. The default is to select only one ERC per use.

EXAMPLE 5 ERC2: Formulation into mixture; ERC6a: Use of intermediate; ERC8a: Widespread uses of non-reactive processing aid (no inclusion into or onto article, indoor).

Table 1 provides an example of the UDS for polymeric nanocomposites. Scenarios for each lifecycle stage are listed, along with a brief description of relevant processes and activities. The table then identifies the process, product, article, and environmental release categories, to provide an overview of uses across the supply chain.

Table 1 — Example of the ECHA use descriptor system of CNT in polymeric nanocomposites

LCS	ES	Short description of process or activity	PROC	SU	Product category	AC	ERC
LCS 1: CNT synthesis	Production/ synthesis of CNTs using chemical vapour deposition	Synthesis	PROC1	—	—	—	ERC1 Manufacture of the substance
		Recovery	PROC2				
		Packing	PROC9				
		Internal transport	PROC8b				
		Cleaning and maintenance	PROC8b				
		Storage and distribution	PROC8b				
	Production/ synthesis of CNT using arc-vapour	Synthesis	PROC1	—	—	—	ERC1 Manufacture of the substance
		Recovery	PROC2				
		Packing	PROC9				
		Internal transport	PROC8b				
		Cleaning and maintenance	PROC8b				
		Storage and distribution	PROC8b				
	Production/ synthesis of CNT using laser ablation	Synthesis	PROC1	—	—	—	ERC1 Manufacture of the substance
		Recovery	PROC2				
		Packing	PROC9				
		Internal transport	PROC8b				
		Cleaning and maintenance	PROC8b				
		Storage and distribution	PROC8b				
LCS 2: CNT Incorporation into products	Manufacturing of intermediate composite materials containing CNTS	Weighing, mixing, loading	PROC5	SU12 Manufacture of plastics products, including compounding and conversion	—	—	ERC1 Manufacture of the substance
		Extrusion and granulation	PROC14				
		Packing	PROC21				
		Internal transport	PROC21				
		Cleaning and maintenance	PROC8b				
		Storage and distribution	PROC21				

Table 1 *(continued)*

LCS	ES	Short description of process or activity	PROC	SU	Product category	AC	ERC
LCS 3: Manufacturing of products containing CNTs	Manufacturing of solid products with composite materials containing CNTs	Weighing, mixing and loading	PROC5	SU12 Manufacture of plastics products, including compounding and conversion	PC32 Polymer preparations and compounds	AC13 Plastic articles	ERC3 Formulation into solid matrix
		Extrusion, moulding and forming	PROC14				
		Shaping and finishing	PROC24				
		Cleaning and maintenance	PROC8b				
		Storage and distribution	PROC21				
LCS 4: Use and service life	Professional use (service life) of solid composite materials containing CNT	Cutting, shaping, drilling, sanding	PROC24	—	PC32 Polymer preparations and compounds	—	ERC11a Widespread use of articles with low release (indoor)
LCS 5: Recycling and end of life	Recycling and disposal of products containing CNTs	Sorting (mechanical, electromagnetical and manual separation)	PROC21	—	PC32 Polymer preparations and compounds	—	ERC12a Processing of articles at industrial sites with low release
		Processing (mechanical and thermal processes)	PROC24				
		Landfill	PROC21				
		Incineration	PROC2				

The descriptors for all of these categories are requested under the registration, evaluation, authorization and restriction of chemicals (REACH) regulation in Europe for the safety assessment of chemical substances (including nanomaterials) and their uses. The information from this assessment is summarized in the REACH chemical safety report (CSR). One key component of that CSR is the ES in which manufacturers or importers set out the conditions for safe use of their substance. This information is essential to many actors in the chemical supply chain in their day-to-day handling of substances (including nanomaterials). For the identification of the ESs associated with a nano-enabled product, the generation of conceptual maps for the product lifecycle is proposed (general diagram in Figure 1). This diagram links the lifecycle stages of a product with potential exposure/release scenarios (defined as those activities from which release is highly probable to occur), receptors (human, water, soil, air, biota) and technological compartments (WWTPs, incinerators, landfill sites). The five lifecycle stages considered are:

a) MNM synthesis,

b) incorporation of MNM into the product (nano-enabled product manufacturing),

c) manufacturing of products containing MNM,

d) use and service life phase, and

e) recycling and end of life.

A full description of the lifecycle, particularly potential use scenarios, can aid in focusing release testing on conditions that are potentially relevant to the product. During the use phase, intended and unintended release of MNM can occur. The unintended release of MNM typically results from non-point sources such as washed off sunscreens in the ocean water or release from other consumer products, while the intended release results from point sources such as a WWTP that uses MNM for groundwater