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

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TECHNICAL REPORT

ISO/TR 22293

First edition
2021-07

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

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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).

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

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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.

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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

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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.

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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 https://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]

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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]

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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

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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

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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.

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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				

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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

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remediation. In Figure 1, green arrows indicate releases to the environment (generally uncontrolled) and possibly resulting in human exposure (workers and consumers) and red arrows indicate MNM release pathways ending up in waste management or end-of-life treatments.

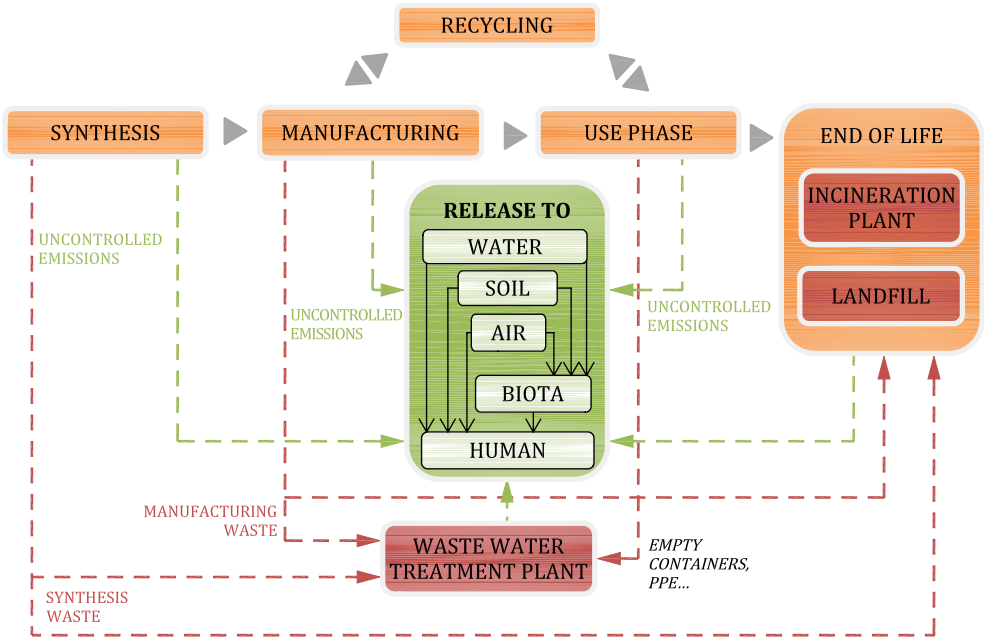

Figure 1 — Lifecycle of a nano-enabled product

5.2 Matrix and MNM characteristics affecting rate and form of release

5.2.1 General

Variations in matrix materials, and MNM types and compositions of nanocomposites can affect the likelihood of nanomaterial release, form of release (e.g. particles containing filler, free filler, degraded filler), and in general the magnitude of materials release, which in turn can each affect measurement method selection.[2] Understanding the physicochemical properties of the neat polymeric matrix material, MNM additive, and composite material is critical in understanding the release behaviour of nanocomposites in their use cases. Potential exposure is often application-specific and is highly dependent on MNM physicochemical properties, the way the MNM is incorporated into the product, and the way the product is being used. Subclause 5.2 briefly reviews key aspects of the physicochemical properties and other key characteristics of the major matrices and MNM additives relevant to nanocomposites to help frame evaluation of the effect of MNM-matrix differences on MNM release characteristics in Clause 6 and the need for particular sampling and measurement methods in Clause 7.

The key topics discussed include:

— release of mnm throughout lifecycle;

— standardized descriptors of nep use, quantification of releases;

— factors affecting MNM release:

  — mnm type,

  — structure/composition of matrix, and

  — product use.

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5.2.2 Consideration of the polymer used in the composite

5.2.2.1 General

To fabricate industrial and consumer NEPs the MNM is usually integrated in a matrix. This matrix is often a designated plastic, i.e. a synthetic material made from a wide range of organic polymers. Plastics are broadly classified as thermosetting or thermoplastic polymers; the classification reflects the post-manufacturing malleability and flexibility. Thermosetting polymers are irreversibly hardened via curing by, for example, heat. Thermoplastic polymers are pliable or moldable at a certain elevated temperature and solidifies upon cooling. The thermal properties depend on the chemical structure and molecular units that form polymer chains and backbones. Thermosetting polymers are often crosslinked forming resins and rubbers (duromers). Understanding the performance differences can help making better sourcing decisions and improve product design.

5.2.2.2 Thermosetting polymers

Thermosetting polymers are made from polymer chains that cross-link together during the curing process to form a permanent chemical bond. Cross-linking that occurs during the curing process prevents movement of individual polymer chains after curing. Because of this, once cured, the structure of thermosetting polymers cannot be altered. This process prevents the product from re-melting when heat is applied, making thermosets ideal for high-heat applications like appliances and electronics. Thermosetting polymers can greatly improve the material's mechanical properties, providing enhanced chemical resistance, heat resistance and structural integrity. Thermosetting polymers are frequently used for sealed products due to their resistance to deformation and are among some of the most impact resistant plastics available. The properties of thermosetting polymers include:

— excellent resistance to solvents and corrosives;

— resistance to high temperatures;

— high fatigue strength;

— tailored elasticity;

— excellent adhesion;

— excellent finishing (e.g. polishing, painting).

The common thermosetting polymers (and applications) include polyester (textiles, 3D printing), vinyl ester (vessels, airplanes), epoxy (adhesives), phenolics (electrical components, household laminates), and urethane (insulating foams, footwear). the most common thermosetting polymers used today is a polyester resin, followed by vinyl ester and epoxy.

5.2.2.3 Thermoplastic polymers

A thermoplastic is a polymeric material or plastic that becomes soft and formable when heated and rigid when cooled. This process can be repeated a number of times without chemically altering the material. Thermoplastic materials offer many performance benefits, such as high strength, shrink-resistance, and easy bendability. Thermoplastic polymers can serve low-stress applications such as plastic bags but are also used in high-stress mechanical parts, depending on the type of thermoplastic material. Thermoplastic materials are highly recyclable, offering aesthetically-superior finishes, high-impact resistance, remolding/reshaping capabilities, chemical resistance, hard crystalline or rubbery surface options, and eco-friendly manufacturing.

Examples of common thermoplastic polymers used today and typical consumer products manufactured from them include Polyethylene Terephthalate (PET) (water and soda bottles), Polypropylene (PP) (packaging containers, automotive parts), Polycarbonate (PC) (windshields, safety glass lenses), Polybutylene terephthalate (PBT) (generic plastic parts, including children's toys), Polyethylene (PE) (packaging, grocery bags), PVC(piping, window frames), Polyethylenimine (PEI) (airplane armrests),

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and Polyamide (PA) (footwear, fishery nets, 3D printing). Table 2 summarizes key features of thermoplastics and thermosetting polymers.

Table 2 — Comparison of important features of thermoplastics and thermoset plastics

Thermoplastic polymers	Thermosetting polymers
can be synthesized by addition polymerization	can be synthesized by condensation polymerization
monomer used is generally bifunctional	monomer used is tri-, tetra- or polyfunctional
long chain linear polymer with negligible cross links	three-dimensional network structure with a number of cross links
low molecular weight	high molecular weight
soft, weak, and brittle	hard, strong, and more brittle
low melting point and low tensile strength	high melting point and high tensile strength

5.2.3 Polymer degradation

All polymers will undergo some degradation during SL. The result will be a steady decline in their mechanical properties caused by changes to the molecular weight, molecular weight distribution, and composition of the polymer. Other possible changes include embrittlement (chain hardening), softening (chain scission), colour changes, and cracking and charring (mass loss). Factors causing polymer degradation include heat, mechanical energy, radiation, ozone, solvents, acids, and bases.

In general, the resistance to degradation will depend on the chemical composition of the polymer. For example, polymers such as PP, PVC, and polybutadiene (PBD) are very susceptible to thermal degradation, even at normal temperature, and can only be prevented from degradation when formulated with UV stabilizers and antioxidants; whereas polymers such as polysulfone (PSU), polyethersulfone (PES), polyetherketone (PEEK), and polysiloxanes (silicones) present excellent resistance to thermal and oxidative degradation due to the strong bonds in the long chain backbones and in the side-groups. The energy applied during processing [mechanical stresses, grinding, ultraviolet (UV) radiation] can cause breakage of bonds. Dissociation energy for the different chemical bonds in a polymer structure ranges from 65 kCal/mol to 110 kCal/mol. These factors can cause degradation of the polymer due to chains scission (by hydrolysis), crosslinking, oxidation, or via other chemical reactions. Oxidation can result in the destruction of crystalline order. Ingredients, additives, or contaminants can undergo radical formation, which then attacks the polymer. However, stabilizers are used to counter various types of degradation processes (e.g. antioxidants, light stabilizers, heat stabilizers, antiozonants).

Furthermore, some properties of the polymer could facilitate oxidation processes: for example, low degree of crystallinity, low molecular weight polymers, higher branching, presence of double bonds in the chemical structure, and the presence of additives leading to free radicals.

5.2.4 Consideration of MNM used in the composite

MNM additives used in composites can be classified based on their composition and geometry. The basic composition can be either organic (e.g. dendrimers, polymers), inorganic (e.g. metals, metal oxides, metal hydroxides), carbon (e.g. carbon nanotubes, bucky-balls), or combinations of these materials. Even more complex systems can be generated by surface functionalization.

The selection of the MNM in the production of nanocomposites depends on the desired properties for the specific application. Specific thermal, mechanical, electrical, magnetic, and optical properties can be obtained or enhanced by inclusion of different MNM into a polymeric matrix. Preparation of MNM-polymer nanocomposites might involve surface modification of MNM because it is important to obtain strong interactions between MNM and polymer to enhance structural features and optimize stable dispersion of the MNM in the nanocomposite. There have been many studies on optimizing the dispersibility of MNM additives in the polymeric matrix. It is possible to increase hydrophobicity of

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the MNM additives via surface modification, enhance interfacial adhesion via chain entanglement or chemical bonding.

Potential MNM additives include those based on carbon, metal oxides, and metals. The properties provided to the composites by the incorporation of these different nano additives is briefly described.

One of the most commonly used carbon-based MNM additive are CNTs. The nature of the atomic arrangements and bonding in CNTs provide these materials with exceptional mechanical properties (tensile strength, elastic modulus, and hardness), very good thermal conductivity, and structure-dependent electrical properties (metallic to semiconducting). These properties, along with low density and large aspect ratios, make CNTs attractive for many applications.[3] Additionally, the incorporation of graphene or graphene oxide in polymeric nanocomposites resulted in significant improvements not only in the mechanical, thermal and electrical activities,[4] but also improvements in the conductivities and gas barrier properties compare to the neat polymer[5].

A wide range of metal oxide-based MNM have proved to provide interesting properties: nanoclays present multiple advantages, they can be obtained from relatively cheap materials (clays). Additionally, their flat morphology makes it much easier to obtain good dispersions into the polymeric matrices[6] and therefore, provides multiple properties (flame retardancy, anticorrosion, gas barrier, increase stiffness and heat distortion temperature).[7],[8] The addition of amorphous SiO_2 into certain polymeric matrices resulted in an improvement of mechanical properties (increasing tensile, impact and strength) as well as evidences of flame-retardant properties have been found.[9],[10] Zinc oxide (ZnO) is an interesting material to be introduced into polymeric matrices due to its antibacterial properties[11],[12] and it is also used in applications such as food packaging[13] to improve food preservation in storage and in some circumstances (actively forming hydrogen bonds) can improve mechanical properties of the composite.[12] TiO_2 nanoparticles (both anatase and rutile polymorphs), which are well recognized for their photocatalytic activity,[14],[15] also are commonly incorporated into polymeric matrices, providing an increase in UV absorption to the nanocomposite, useful for multiple applications. The incorporation of TiO_2 nanoparticles in some polymers resulted in an increase in the tensile modulus, decomposition temperature, dimension stability, bending stress, impact stress and elongation break[16],[17].

Finally, considering the incorporation of metal-based MNM, Silver (Ag) is one of the most interesting MNM additives due to its unique electric, optical, catalytic and, particularly, antimicrobial properties.[18] For this reason, its incorporation into polymers have been widely studied and tested.[19] When combined with polymers, if correctly dispersed and designed, the resulting nanocomposite acquires antibacterial properties that are useful for many applications (e.g. medical devices area)[18].

The selection of MNM to use in a nanocomposite and preparation of the MNM nanocomposite might affect release sampling, sample preparation, and analytic needs as discussed in Clauses 6 and 7.

5.2.5 Polymer nanocomposites

Scientific and technological development in recent years has allowed the incorporation of different nanoscale compounds (e.g. carbon nanotubes, metal oxide nanoparticles, nanoclays) into polymer matrices. The incorporation of those additives can change some properties of the matrix, due to the large surface area to volume ratio of nanomaterials when compared to the microscale or macroscale additives. The dispersion of a MNM in the polymer matrix can introduce new physical properties and novel behaviours compared to the original matrices, effectively changing the nature of the original matrix. This can be used to produce either advanced materials with improved properties or new applications, or both.[20] These properties and applications are important to consider in terms of how they might affect release measurement needs. For example, nanocomposite rubber tires with everyday use account for more than one megaton per year of carbon black and silica production in the nanoscale range. However, degradation of rubber nanocomposite tire tread during use is a prime example of the challenge of measuring MNM release during the use phase of lifecycle.[21] Furthermore, major innovations might soon drive rapid growth of the “highly dispersible (HD)” silica additives that are replacing carbon black and so standard methods to measure MNM release must be adapted to changing properties of the tires as innovations proceed. The use of MNM in tires is also unusual because it represents a nanocomposite with very high filler content (above 40 % by weight), whereas the additive content of most other nanocomposites is in the 1 % to 5 % range.

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Products that contain MWCNTs are manufactured from composite made from MWNCTs incorporated in a polymer matrix. Five polymers that are commercially relevant and represent a range of polymer characteristics are epoxy (EP), PA, polyurethane (PU), PE, and PC (see also Table 2). Composites used for final products are typically formulations of the polymer and additives designed to modify the physicochemical characteristics of the polymer, particularly its mechanical properties (strength, toughness, and wear resistance) and chemical and thermal resistance to degradation.

The development of other polymer nanocomposites is a growing area in all the industrial sectors. Over the past decade, these MNM filled compounds have attracted considerable interests in both academia and industry, owing to their outstanding variety of properties with only a small amount of MNM additives. Examples include mechanical (e.g. elastic stiffness and strength),[22],[23] physical (e.g. barrier resistance, flame retardancy or scratch resistance),[7] electrical,[24] magnetic,[25] thermal, and optical properties. These new nanocomposites enable interesting applications in most of the industrial sectors, with a particularly high incidence in the electronics, automotive, textile, and mining sectors.

Polymer nanocomposites will not only expand the performance space of traditional filled polymers but also introduce completely new combinations of properties, and thus enable new applications for plastics.[26],[27] Low volume additions (1 % to 5 %) of nanoparticles, such as layered silicates or carbon nanotubes, provide property enhancements (with respect to the neat resin) that are comparable to those achieved by conventional loadings (15 % to 40 %) of traditional fillers. The lower loadings facilitate processing and reduce component weight. Most important, though, is the added unique properties, such as reduced permeability, optical clarity, self-passivation, and increased resistance to oxidation and ablation, not normally possible with traditional additives. These characteristics have been transformed into numerous commercial successes, including automotive parts, coatings, and flame-retardants.

5.2.6 Application areas and use phase (or lifecycle) processes

The end user could be intentionally or unintentionally exposed to MNMs as a result of NEP use. During common use of the products, the end user can be subjected to various controllable and uncontrollable conditions, which might increase the potential for the release and transformation of the MNMs. Released MNMs are often different from the pristine parent material in terms of size and aggregation and agglomeration state, and they can be released either as free MNMs or together with fragments of the product matrix. The use phase will, in most cases, be the most important part of the lifecycle for consumer exposure to MNMs. The analysis of the needs for release measurement methods for each product and product category will require a separate evaluation of the use scenario that accounts for the product design, how it is used, and the resulting potential conditions of MNM release. The way a MNM is incorporated or applied in the product will have a high influence on the MNM properties and the potential for being released and subsequently leading to consumer or environmental exposure.

Through consumer product use, disposal, or recycling, nanocomposites encounter mechanical, thermal, and/or chemical energy inputs that could degrade the nanocomposite and result in the release of the embedded nanomaterials. Several studies cited in this section below investigated release of MNM from polymer nanocomposites in different scenarios (weathering, abrasion, sanding, incineration). From these studies, it is observed that there are generally insufficient data generated to support decision making about MNM release rates using a common and harmonized methodology. However, after analysing the methods used in each case, one could establish some parameter ranges for each process to experimentally simulate real conditions using different laboratory simulations. Laboratory simulations can lead to the following potential erroneous conclusions:

— The stresses of the laboratory simulation tests might not be representative of the stresses by the intended use or operational conditions or handling; for example, the machining tool used in the laboratory experiments might have different characteristics than the one used by the operator or consumer; or, self-ignited thermal decomposition might not reflect the conditions of waste incinerators:

  — risk: the form of release and rate of release would be incorrectly determined;

  — mitigation: recommends stressing the nanocomposite by established ISO protocols that represent real-world scenarios. For example, the NanoRelease weathering protocol uses the

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established ISO 4892-3[231] for the aging of the polymer nanocomposites, before sampling and analysis. Furthermore, 5.2.6 lists characteristics of tools.

— The static emission measurements are performed; for example, aerosols from sanding might accumulate and agglomerate, or, leachates might reach saturation:

  — risk: weak correlation from sanding emission to human exposure in the breathing zone. Simulated leaching might underestimate environmental leaching.

  — mitigation: more than one concentration of nanocomposite should be tested.

One should also consider different situations such as:

— The nanocomposite might contain an MNM that is known to be hazardous:

  — risk: the field test will put either operators or the environment, or both, at risk;

  — mitigation: use the options of containment in a laboratory simulation.

— The release rates are often low:

  — risk: the industrial or environmental background might conceal the released fragments of the nanocomposite;

  — mitigation: use the options to reduce background in laboratory simulations, for example, by testing in ultrapure water or in HEPA-filtered sanding boxes.

— In early stages of research, only small amounts of the nanocomposite might be available:

  — risk: unavailability of a sufficient amount of nanocomposites;

  — mitigation: use laboratory simulation testing to require less sample material.

Further limitations of experimental conditions could be possible, depending on the specific product and potential use scenarios.

For example, Table 3 lists different methods or processes used to induce release for PA polymer nanocomposites containing MWCNT, including conditions applied in each of the scenarios studied.

NOTE All of these studies involved laboratory simulations.

Table 3 — Experimental conditions for releases from different processes

Process or cause for release	Description	References
Weathering	UV = 60 W to 480 W (in 300 nm to 400 nm wavelength intervals) for 1 000 h in an accelerated chamber, equivalent to approximately 1 year to 3 year in real conditions based on ISO 4892-3[231]	[28], [29], [30], [31], [32], [33], [34], [35], [36], [37]

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Table 3 *(continued)*

Process or cause for release		Description	References
Sanding	Manual sanding	Manually sanded epoxy test sticks with sandpaper (220 grit)	[38], [39]
	Sandpaper affixed to a rotational disk plate	Three levels of sandpaper roughness (ADSLOX A290 P80, P150 and P320) were used, adhesively affixed to the surface of a disk plate fixed onto a lathe	[40], [41]
	Hand-held sanding equipment	A miniature sander (Model Dremel 400 series) with a contact force of $2{,}0 \times 10^{-1}$ N to 1,0 N, contact pressure of $1{,}0 \times 10^{4}$ to $5{,}0 \times 10^{4}$ and peripheral speed of 1,8 m/s to 24 m/s or a hand-held sanding machine (Metabo FSR200 with 22 000 oscillations/min was used	[42], [43]
	Sanding belt	A belt sander (Model 97181) with a sanding belt (10,2 cm × 91,4 cm) operating at a constant speed of 5,6 m/s with a silicon-aluminium based sandpaper having grit sizes of P150 and P320	[39], [44]
Abrasion		Taber equipment with H-18 abrasive wheel, an applied weight of 0,75 kg and a frequency of 60 c/min	[45]
Band saw		A 220 blade grit, a 1,65 mm blade width, 20 m/s blade speed and 0,2 cm/s to 0,4 cm/s rate of advance of the composites in dry and wet ambient environment	[39], [43], [46]
Rotatory cutting wheel		A 220 blade grit, a 1,65 mm blade width, 15 m/s blade speed and 0,4 cm/s rate of advance of the composites in wet condition (water flushing)	[46]
Drilling		725 rpm to 1 355 rpm drilling speed, 17 N normal load, and 1,3 mm to 3,9 mm specimen thickness, performed under dry and wet ambient conditions	[47], [48]
Scratching		Normal load of 5 N to 25 N, scratch length of 5 mm at 5 mm/min speed for a total of one to 15 scratches	[49]
Crushing		7 900 rpm to 18 750 rpm rotation speed at 108 mm crushing chamber diameter; 14 thousand total rotations	[50]
Incineration		The lab simulations of waste incineration reproduced ISO 15270, which requires a furnace temperature of at least 850 °C (1 562 °F), after overfire, air injection of at least 2 s, and oxygen concentration of 20,9 vol %. Only for hazardous waste incineration, ISO requires temperatures up to 1 200 °C (2 192 °F), but were not yet tested.	[51], [52], [53], [54]

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Table 3 *(continued)*

Process or cause for release	Description	References
Food contact	Release has been observed for NEPs that were tested for contact with vinegar, alcoholic beverages, flavour extracts, and the like, simulated in food contact standards by 3 % acetic acid and 50 % to 95 % ethanol. The release was dominated by MNM dissolution inside the NEP matrix in these cases.	[55], [56], [57]

The processes or causes listed in Table 3 for release of MWCNT from PA composites describe rigorous conditions that could also be applied for other composite and MNM additive combinations. However, as noted, although the extremes of some of the test conditions reflect the relatively short test periods, further consideration of the use scenario might allow the developers of a testing program to focus on a subset of specific potential release mechanisms, under conditions that more closely mimic potential end use conditions.

6 Factors affecting release measurement method selection

6.1 General

The available literature has extensively evaluated the effect of release mechanisms as described in 5.2.6 (e.g. abrasion, chemical, thermal) and conditions (e.g. temperature, pH, release media) on the forms of materials that would be released, and amounts of release materials that can occur (red triangle in Figure 2).

For the purpose of this document, release is defined as the first release of material from an MNM containing composite into exposure or effluent pathways during consumer or commercial use of the product (see Figure 2). Subsequent fate and transport and determination of resulting exposures are beyond the scope of this document. Release can occur through processes such as physical, chemical, or thermal degradation of polymer matrix resulting in particles that could include a mixture of free MNM additive, matrix-bound MNM additive, and matrix without MNM additive. Subsequent MNM additive release could follow from this first release. For example, MNM additive could eventually be released from the initially released particles as those particles degrade in the environment; however, these subsequent release events will not be addressed in detail in this document.

The sampling and measurement methods discussed in this document are targeted for the size range from few nanometres to several micrometres, as these size ranges are relevant to inhalation, dermal, or incidental ingestion exposure events.

The key topics covered include:

— size range, toxicity, form of release, mnm/matrix resilience;

— identification/evaluation of release concerns;

— relevant scenarios.

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