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# Nanotechnologies — Guidance for the responsible development of nanotechnologies

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## National foreword

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# Nanotechnologies - Guidance for the responsible development of nanotechnologies

Nanotechnologies - Guide pour le développement responsable des nanotechnologies

Nanotechnologien - Leitfaden zur verantwortungsvollen Entwicklung von Nanotechnologien

This Technical Specification (CEN/TS) was approved by CEN on 22 March 2016 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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## European foreword

This document (CEN/TS 16937:2016) has been prepared by Technical Committee CEN/TC 352 “Nanotechnologies”, the secretariat of which is held by AFNOR.

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

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

# Introduction

Nanotechnology-related development brings novel functionalities to materials, and new applications. They have been accompanied by a societal demand to assess their effects, given the lack of (reliable) information related to this novel area. While assessing risks, benefits, lack of (reliable) information, or ambiguity, is not specific to this field, the question of responsible development, including societal and ethical aspects, is often raised in the context of nanotechnologies. As the technology matures, lack of (reliable) information should be reduced and the risks associated with the use of such technology should be minimised. Ambiguity may arise in presence of contradictory scientific results and diversity of opinions, and should as far as possible be reduced over time. Making appropriate decisions regarding policy, strategy, human health and the environment, safety or communication in nanotechnology is therefore a task that most small, medium and large organisations involved in this field face today.

It is therefore clear that making the right decisions in an open, transparent and balanced manner is critical for industry to continue to develop nanotechnologies responsibly.

Organisations working in the nanotechnology area should ensure to develop and implement an appropriate set of norms with the same approach for all products or services of the organization.

To ensure the responsible development of nanotechnologies, this Technical Specification (TS) provides a guidance to communication and interaction with relevant stakeholders. It describes the process that an organization or group of organisations may choose to follow to ensure accountability, transparency, safety (for workers, consumers, and for the environment) and clear communication.

The approach proposes to compare benefits and risks of nanotechnology activities, and seeks to encourage the implementation of preventive or corrective actions before commercialisation (such as design modification).

This Technical Specification can be used by organisations working in nanotechnology supply chains, academia, policy makers and non-governmental organisations (NGOs). This Technical Specification may also be used by the organisations providing services to the industry such as consulting, finance or insurance companies.

This Technical Specification provides guidance that does not supersede or substitute for any applicable legal requirements.

# 1 Scope

This Technical Specification provides a guidance for the responsible development of nanotechnologies taking into account:

— Board Accountability;

— Stakeholder Involvement;

— Worker Health and Safety;

— Benefits to and Risks for Public Health, Safety and the Environment;

— Wider Social and Ethical Implications and Impacts;

— Engagement with Business Partners;

— Transparency and Disclosure.

NOTE 1 This Technical Specification contributes to social responsibility as defined in ISO 26000:2010.

NOTE 2 Nanotechnology activities include industrial production, R&D, services, and marketing of products.

This Technical Specification neither covers labelling and advertising aspects nor is it intended for certification purposes, nor does it imply any legally binding agreements.

This Technical Specification intends to cover nanotechnology activities involving manufactured nanomaterials, and where relevant incidental nanomaterials.

# 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CEN ISO/TS 80004-1:2015, *Nanotechnologies – Vocabulary – Part 1: Core terms (ISO/TS 80004-1:2015)*

# 3 Terms and definitions

For the purposes of this document, the terms and definitions given in CEN ISO/TS 80004-1:2015 and the following apply.

**3.1**
**ambiguity**
plurality of legitimate viewpoints, multiple values and perspectives for both conducting and evaluating the science and information used for decision-making, for the interpretation of decision outcomes and justifying judgements about their tolerability and acceptability

**3.2**
**benefit**
positive impact(s) to stakeholders such as consumers, citizens or companies, related to the nanotechnology activity

Note 1 to entry: Environmental aspects are included.

**3.3**
**consumer**
individual member of the general public purchasing or using property, products or services for private purposes

[SOURCE: ISO 26000:2010, 2.2]

**3.4**
**incidental nanomaterials**
nanomaterial (3.6) generated as an unintentional by-product of a process

Note 1 to entry: The process includes manufacturing, bio-technological or other processes.

Note 2 to entry: See "ultrafine particle" in ISO/TR 27628:2007, 2.21.

[SOURCE: CEN ISO/TS 80004-1:2015, 2.10]

**3.5**
**manufactured nanomaterial**
nanomaterial (3.6) intentionally produced to have selected properties or composition

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

**3.6**
**nanomaterial**
material with any external dimension in the nanoscale (3.7) or having internal structure or surface structure in the nanoscale

Note 1 to entry: This generic term is inclusive of nano-object (CEN ISO/TS 80004-1:2015, 2.5) and nanostructured material (CEN ISO/TS 80004-1:2015, 2.7).

Note 2 to entry: See also engineered nanomaterial (CEN ISO/TS 80004-1:2015, 2.8), manufactured nanomaterial (3.5) and incidental nanomaterial (3.4).

[SOURCE: CEN ISO/TS 80004-1:2015, 2.4]

**3.7**
**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: CEN ISO/TS 80004-1:2015, 2.1]

**3.8**
**nanotechnology**
application of scientific knowledge to manipulate and control matter predominantly in the nanoscale (3.7) to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules or extrapolation from larger sizes of the same material

Note 1 to entry: Manipulation and control includes material synthesis.

[SOURCE: CEN ISO/TS 80004-1:2015, 2.3]

**3.9**
**organization**
entity or group of people and facilities with an arrangement of responsibilities, authorities and relationships and identifiable objectives

Note 1 to entry: For the purposes of this International Standard (ISO 26000:2010, 2.12), organization does not include government acting in its sovereign role to create and enforce law, exercise judicial authority, carry out its duty to establish policy in the public interest or honour the international obligations of the state.

Note 2 to entry: Clarity on the meaning of small and medium-sized organizations (SMOs) is provided in ISO 26000:2010, 3.3.

[SOURCE: ISO 26000:2010, 2.12]

**3.10**
**product**
any goods or service

[SOURCE: EN ISO 14040:2006, 3.9, modified – deletion of Notes 1 to 3]

**3.11**
**professional user**
user with recognized competence to select and use products appropriate to its profession, without direct supervision, but not necessarily having control over which products are purchased for use in its workplace

**3.12**
**risk**
effect of uncertainty on objectives

Note 1 to entry: An effect is a deviation from the expected —, positive and/or negative.

Note 2 to entry: Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process).

Note 3 to entry: Risk is often characterized by reference to potential events (ISO Guide 73:2009, 3.5.1.3) and consequences (ISO Guide 73:2009, 3.6.1.3) or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (ISO Guide 73:2009, 3.6.1.1) of occurrence.

Note 5 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence or its likelihood

Note 6 to entry: In the context of this Technical Specification, risks are related to negative effects, and benefits (3.2) are related to positive effects. Nanotechnology risk evaluation and management is further described in ISO/TR 13121:2011 and ISO/TS 12901-1:2012 and ISO/TS 12901-2:2014.

[SOURCE: ISO Guide 73:2009, 1.1, modified – addition of a new Note 6 to entry]

**3.13**
**stakeholder**
individual or group that has an interest in any decision or activity of an organization (3.9)

[SOURCE: ISO 26000:2010, 2.20]

# 4 Methodology

## 4.1 General

The methodology is composed of seven sections addressed in the scope. Following this Technical Specification only partially may make it more difficult to demonstrate to other stakeholders the fundamental principles in a responsible development such as accountability, transparency, safety (workers, consumers safety and environmental safety) and communication. The user of this Technical Specification is therefore advised to implement the responsible methodology in its entirety (all seven sections) as described below.

Due to issues of translation to other languages (e.g. French or German) it is important to remind the user that neither “accountability” nor the “responsibility” are to be understood as legal obligations in the context of this Technical Specification.

## 4.2 Board Accountability

The user of this Technical Specification should ensure appropriate accountability at management level. Appropriate staff should be assigned in the organization to deal with accountability in guiding and managing the development in nanotechnology.

The appointed staff should consider, understand, assess and minimize any adverse human health, environmental and safety, societal and ethical issues associated with the organization’s involvement with nanotechnology activities.

## 4.3 Stakeholder Involvement

The user of the Technical Specification should identify the concerned stakeholders and proactively engage with them. The engagement should be more than just information dissemination and should provide a platform for a multilateral dialogue.

Stakeholders may (not exclusively) involve workers, customers (business-to-business and end-consumers), shareholders, suppliers, non-governmental organisations (NGOs), civil society organisations, academics, consumer bodies, trade unions, national governments, international governing bodies and the general public.

The user of the Technical Specification should be able to demonstrate how stakeholder views have been considered. As agreement with all stakeholders is not always possible the organization should be able to justify the decisions taken in the case of lack of agreement.

The user should define with stakeholders how they will be involved. Indeed stakeholders might be involved under different perspectives, like but not limited to understanding and advising on the function of the product, identifying alternatives, defining metrics to assess the risks and the benefits, understanding and resolving lack of (reliable) information and ambiguities (for instance regarding the risk assessment).

The user of the Technical Specification and the stakeholders initially engaged in the process should decide in common at an initial stage whether the situation needs to include additional stakeholders.

More emphasis on the involvement of stakeholders, and a diversity of stakeholders is relevant in situations where risks or benefits are particularly complex, where there is a significant lack of (reliable) information, and especially if there is ambiguity.

## 4.4 Worker Health and Safety

The organization should ensure high standards of occupational health and safety for its workers. The arrangements for the protection and safety of workers shall satisfy all regulatory requirements imposed by regulators. Such requirements shall be met before using this Technical Specification and should be considered as a minimum set of requirements.

Risks for workers should be assessed and minimised using the most up-to-date guidelines. The results of the assessment, the decisions, the relevant standards and protocols used to ensure a high standard of health and safety of staff should be clearly communicated.

Open and transparent reporting of any safety breaches and potential effects on workers should be available to workers and relevant stakeholders. Lessons learned from incidents and accidents should also be shared, respecting personal or other informational rights.

## 4.5 Benefits to and Risks for Public Health, Safety and the Environment

The organization should conduct, in preference at the design and planning stage, a thorough risk assessment, taking into account the existing standard for risk assessment ISO 31000, and, if relevant, other specific guidances. Any potential public health, safety and environmental risks relating to the processes and all other activities in connection with development in nanotechnology should be minimised. The user of the Technical Specification should put in place a process addressing the risk to public and the environment, and applying to all products and decisions in the organization. Under this process, risk should be minimised at or below the level required by the regulators, or below the level defined through engagement with stakeholders.

The organization should consider sharing the best practice in safety and risk management of nanotechnology-related innovation with regulators and standardization organisations.

The benefit and risk assessment should be performed on a regular basis in order to take into account any of the development in technology, risk science, process efficiency, new standardization guidelines or regulatory changes.

Furthermore, this assessment should take into account any possible lack of (reliable) information related to this novel technology area.

The benefit and/or risk assessment should consider alternatives (nano or non-nano) to the envisioned nanotechnology activity (performing the same or a similar function or service).

NOTE 1 Guidance on comparative assessment of alternatives can be found in (OECD, 2013).

The following approach is based on three steps as follows:

The **first step** deals with the identification and the description of the nanotechnology activity. At this stage the functionality, the use patterns and supply chains of the nanotechnology activity are defined. This involves describing the nanotechnology in use (or considered for future use).

NOTE 2 It could be appropriate to define also the geographic area affected by the assessment, taking into account both the market for the nanotechnology and the area concerned by the end-of-life.

When this activity involves design, production, use, release, or disposal of nanomaterials, the physic-chemical characterization should be carried out according to the existing standards (in particular, ISO/TC 229 standards).

Criteria are needed to identify incidental nanomaterials. The user should justify where and when incidental nanomaterials are not taken into account in the assessment.

The aim of the **second step** is to undertake a benefit assessment and a risk assessment of the nanotechnology activity, in comparison with relevant alternatives, and to identify any lack of (reliable) information.

The assessment should take into account the life cycle aspects (see also EN ISO 14040 and WI 00352011 “Guidelines for aspects of life cycle assessment specific to nanomaterials” under preparation by CEN/TC 352/WG 3, and OECD, 2015).

The risks to different exposed populations and for the environment should be taken into account along the life cycle, as well as exposure of populations via the environment.

For workers (involved in production or use phases) the user of the Technical Specification could follow the specific standard for workers on control banding, in particular; ISO/TS 12901-1:2012 and ISO/TS 12901-2:2014.

For consumers and professional users, direct and indirect exposures should be both considered.

When the nanotechnology activity involves design, production, use, release, or disposal of nanomaterials, the substances used for functionalization, and, when applicable, the main known incidental nanomaterials should be taken into account in the risk assessment.

NOTE 3 Specific risk assessment techniques could be required to assess specific (eco)toxicity risks and impacts. There are already different proposed frameworks of simplified risk assessment associated with a nanotechnology activity (OECD 2014).

There are several potential methods to assess benefits to stakeholders of introducing a product with a function or a service. When the nanotechnology activity brings a new function, for which no previous reference is available, the user of the Technical Specification should describe at least qualitatively the added value in comparison with the closest existing alternative. The energy consumption involved in the nanotechnology activity should be taken into account in the benefit assessment. Overviews and guidance can be found in OECD, 2002, ECHA, 2008, or US-EPA, 2010.

The **third and final step** is to compare risks and benefits taking into account the lack of (reliable) information and decide whether and/or under which conditions to develop the nanotechnology activity. The output of the final step can also be to take actions to improve the reliability of information, and/or to reduce the level of risk, and/or to increase the benefits.

Another possible outcome is to change the design (or intended applications) of the nanotechnology activity.

The benefits of the products should not be overstated or exaggerated to the best knowledge of the user. The use of a nanotechnology should not be taken systematically as a sign of enhanced product performance or functionality. Nor should it indicate systematically any increased risk to users.

Several approaches are possible to facilitate this decision, but the user should always make an explicit and justified choice of a particular method: where appropriate, decision rules, decision trees, scoring and weighting (multicriteria analysis or MCA), or a Cost/Benefit Analysis (CBA) may be considered.

Whatever the method used, the user of the Technical Specification should take into account the distribution of benefits and risks within the value chain and among stakeholders.

Approaches chosen should involve stakeholders in a deliberative process of mutual learning and key choices, and potential changes over the years should be transparent and justified.

**An estimate of the reliability of the assessment** shall be considered as a key feature when assessing benefits and risks.

The user of the Technical Specification should especially consider the lack of (reliable) information in the following areas:

- physical characteristics such as shape, number, size distribution at the initial stage and its evolution during the service life and the end of life of products;
- chemical characteristics;
- biological activity;
- toxicology and ecotoxicology;
- exposure scenarios;

- use patterns: how downstream users or recyclers will actually reuse, recycle or dispose the product;
- markets development scenarios: consider the possible parallel development of competing alternatives.

## 4.6 Wider Social and Ethical implications and impacts

Involvement in nanotechnology development can have wide social and ethical implications, especially as an enabling technology that has close connection with information technology and biotechnology.

Social and Ethical implications go beyond the Health, Safety and Environmental issues addressed above and are very specific to each nanotechnology area. They can encompass such issues as (un)equal access to technology and its benefits, possible enhancement of ethically controversial activities through nanotechnology, and impacts of nanotechnology on humankind definition and situation. Identification of relevant ethical concerns should be carried out with the engaged stakeholder group.

Through observance of this Technical Specification and especially of its communication and transparency principles, the user will anticipate and address potential social and ethical aspects of nanotechnologies.

## 4.7 Engagement with Business Partners

The user of this Technical Specification should communicate with other actors along the value chain. Wherever possible, the results of the implementation of this Technical Specification should be made available for the business partners of the user.

The user should provide appropriate information for the onward users of nanotechnology in the life cycle of affected products (e.g. processing, usage, transportation, storage, disposal, re-use or recycling) to enable them to follow the Technical Specification.

The user should more generally engage proactively with its business partners (e.g. academic institutions, suppliers, contractors, transport operators, distributors, marketing services and business customers) to encourage the use of the Technical Specification throughout the entire supply chain.

If the actions following the implementation of this Technical Specification are to set conditions to the commercialisation, these conditions need to be materialized by contracts, partnership approaches, feedback collection and analysis procedures that may involve business partners.

NOTE "Actor" is here defined as "entity which characterizes a role played by a user or any other system that interacts with the subject".

## 4.8 Transparency and Disclosure

The user should be open and transparent about its nanotechnology activities in its processes, products or waste management. The user of the Technical Specification should take steps to clearly communicate the advantages and disadvantages (or benefits and risks) of these nanotechnology activities, according to the assessment carried out in 4.5, through open disclosure in websites, annual reports, voluntary public disclosure schemes, product databases, voluntary labelling, seminars or conferences. A description of lack of (reliable) information and ambiguities should also be communicated under this process.

The communication with stakeholders should be on a regular basis, and adapted to the pace of innovation. Adherence to the methodology of this Technical Specification should be clearly communicated and any deviation should be explained and justified. In the light of new scientific evidence some of the processes may be revised on a regular basis and such changes should also be clearly communicated. Nanotechnology related scientific evidence may have limited level of maturity or contradictory results leading to lack of (reliable) information and/or ambiguity. Both should be considered, communicated to, and discussed explicitly with stakeholders.

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