



**SLOVENSKI STANDARD**  
**kSIST-TS FprCEN/TS 16937:2016**  
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**Nanotehnologija - Navodila za odgovoren razvoj nanotehnologije**

Nanotechnologies - Guidance for the responsible development of nanotechnologies

Nanotechnologien - Leitfaden zur verantwortungsvollen Entwicklung von  
Nanotechnologien

Nanotechnologies - Guide pour le développement responsable des nanotechnologies

**Ta slovenski standard je istoveten z: FprCEN/TS 16937**

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**Nanotechnologies - Guidance for the responsible  
development of nanotechnologies**

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This draft Technical Specification is submitted to CEN members for formal vote. It has been drawn up by the Technical Committee CEN/TC 352.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## European foreword

This document (FprCEN/TS 16937:2015) has been prepared by Technical Committee CEN/TC 352 “Nanotechnologies”, the secretariat of which is held by AFNOR.

This document is currently submitted to the Formal Vote.

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## 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 intendeds 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.

FprCEN 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 FprCEN 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.

**FprCEN/TS 16937:2015 (E)****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: FprCEN ISO/TS 80004-1:2015, 2.10]

**3.5****manufactured nanomaterial**

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

[SOURCE: FprCEN 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 (FprCEN ISO/TS 80004-1:2015, 2.5) and nanostructured material (FprCEN ISO/TS 80004-1:2015, 2.7).

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

[SOURCE: FprCEN 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: FprCEN 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: FprCEN 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.