

English Version

## 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.

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

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<b>Contents</b>	<b>Page</b>
<b>European foreword</b> .....	<b>3</b>
<b>Introduction</b> .....	<b>4</b>
<b>1 Scope</b> .....	<b>5</b>
<b>2 Normative references</b> .....	<b>5</b>
<b>3 Terms and definitions</b> .....	<b>5</b>
<b>4 Methodology</b> .....	<b>8</b>
4.1 <b>General</b> .....	<b>8</b>
4.2 <b>Board Accountability</b> .....	<b>8</b>
4.3 <b>Stakeholder Involvement</b> .....	<b>8</b>
4.4 <b>Worker Health and Safety</b> .....	<b>8</b>
4.5 <b>Benefits to and Risks for Public Health, Safety and the Environment</b> .....	<b>9</b>
4.6 <b>Wider Social and Ethical implications and impacts</b> .....	<b>11</b>
4.7 <b>Engagement with Business Partners</b> .....	<b>11</b>
4.8 <b>Transparency and Disclosure</b> .....	<b>11</b>
<b>Bibliography</b> .....	<b>12</b>

## 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.