TECHNICAL SPECIFICATION

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Nanotechnologies — Guidance on voluntary labelling for consumer products containing manufactured nano-objects

Nanotechnologies — Lignes directrices pour l'étiquetage volontaire des produits contenant des nano-objets manufacturés

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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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 229, *Nanotechnologies*.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions.

Click on the link below to take part in the online survey:

https://www.surveymonkey.com/s/ISO_TS_13830

Introduction

It is generally agreed that nanotechnology brings benefits and better performance to enabled consumer products along with possible concerns for adverse effects, which both raise issues about the public awareness on the benefits and concerns.

As nanotechnology is implemented more broadly, the number of products using nanotechnology, in particular the consumer products containing manufactured nano-objects, will increase. Any approach to affixing a label to consumer products containing manufactured nano-objects (PCMNOs) should ensure accurate communication about the product and its properties and avoid misleading labelling.

It is important that sufficient openness and transparency accompany the responsible introduction of new technologies to the marketplace. Labelling can help consumers to make informed choices for purchase and use. The labelling specified by this Technical Specification does not attempt to prejudge either the positive or negative effects of consumer products containing manufactured nano-objects. The purpose of the guidance in this Technical Specification is to provide a framework to facilitate a harmonized approach for the voluntary provision of labelling for PCMNOs that may or may not exhibit or impart nanoscale phenomena. This Technical Specification is designed as voluntary guidance on conveying specific product information that a manufacturer may choose to disclose on product labels and is not intended to provide mandatory labelling requirements, which are established by relevant regulatory authorities.

This Technical Specification is designed for use by businesses and other organizations involved in the manufacture and distribution of consumer PCMNOs. In order to conform to this Technical Specification, all the normative clauses of this Technical Specification apply. A decision about whether to use this Technical Specification is subject to voluntary consideration. Other parties such as authorities, healthcare professionals, consumers, consumer organizations, environmental NGOs and trade unions may also find it useful.

This Technical Specification provides guidance that does not supersede or substitute for any applicable legal requirements. Product manufacturers and distributors are advised to identify and understand applicable legal requirements and guidance issued by regulatory authorities. Products intended for sale in a specific country or region should conform to, and the use of this document should not conflict with, legal requirements for product labels and labelling established for that country or region.

Nanotechnologies — Guidance on voluntary labelling for consumer products containing manufactured nano-objects

1 Scope

This Technical Specification provides guidance on the content of voluntary labels for consumer products containing manufactured nano-objects (PCMNO).

This Technical Specification is not applicable to consumer products that contain naturally occurring nano-objects that were not subjected to manufacturing processes. Consumer products containing nano-objects that are incidentally present (i.e. unintentional by-products of a process) are also outside the scope of this Technical Specification.

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.

ISO/TS 80004-1, *Nanotechnologies — Vocabulary — Part 1: Core terms*

3 Terms and definitions

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

3.1
consumer product
product that is intended to be acquired and used by an individual for personal rather than professional use, excluding its packaging

[SOURCE: ISO 20282-1:2006, 3.2 — modified]

3.2
label
written, printed, graphic matter affixed to a product, imprinted on a product, or its immediate container or packaging, which displays information related to the product

3.3
labelling
provided information about a product by means of the label affixed to a product, its immediate container or packaging by a manufacturer or supplier

3.4
manufactured nano-object
MNO
nano-object intentionally produced for commercial purposes to have specific properties or composition

[SOURCE: ISO/TS 12805, 3.3]

3.5
nano-object
material with one, two or three external dimensions in the nanoscale

Note 1 to entry: Generic term for all discrete nanoscale objects.

[SOURCE: ISO/TS 80004-1:2010, 2.5]

3.6
nanoscale
size range from approximately 1 nm to 100 nm

Note 1 to entry: Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits should be considered approximate.

Note 2 to entry: The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.

[SOURCE: ISO/TS 80004-1:2010, 2.1]

3.7
nanoscale phenomenon
effect attributable to nano-objects or nanoscale regions

[SOURCE: ISO/TS 80004-1, 2.13]

3.8
nanotechnology
application of scientific knowledge to manipulate and control matter in the nanoscale in order to make use of size- and structure-dependent properties and phenomena, as distinct from those associated with individual atoms or molecules or with bulk materials

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

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

3.9
products containing manufactured nano-objects
PCMNO
products in which manufactured nano-objects are intentionally added, attached or embedded

4 Content of label

4.1 General

Any voluntary statement on a label (i.e. labelling) about manufactured nano-objects present in consumer products should be accurate, substantiated and not misleading. Such labelling should be consistent with other information about the PCMNO. Statements on a label about the manufactured nano-object should neither suggest an improvement that does not exist nor overstate the contribution of the manufactured nano-objects to the product. Statements should not suggest that a PCMNO is endorsed or certified by any organization if it is not. Symbols such as asterisks may be used to draw consumers' attention to additional words or statements.

The organization preparing the label should be able to substantiate the labelling (i.e. the content of the label) discussed in this Technical Specification with reliable information. This information should be maintained and may be obtained from a variety of sources, such as a website, the published literature, or reproducible and validated scientific data.

The labelling conforms to this Technical Specification only when it conforms to the specific recommendations given herein; however the manufacturer has flexibility in interpreting how to implement those recommendations.

4.2 Content

4.2.1 Identification and description of manufactured nano-objects

Manufacturers may voluntarily disclose the presence of manufactured nano-objects in consumer products, provided that such disclosure on the label does not conflict with any applicable legal requirements. For such voluntary labelling, information that the consumer product contains manufactured nano-objects should be provided either:

— as part of an ingredient list on the label by placing the term “nano” or “nanoscale” before or after the commonly used name of the manufactured nano-object, unless the name already contains it, e.g. carbon nanotubes; or,

— by placing the phrase “contains manufactured nano-objects” on the label.

Where it is possible, the first option is preferable.

If available, a concise description of the effect of the manufactured nano-object in the product may be provided, in relation to both beneficial and risk aspects, to inform consumers and to facilitate information exchange. In addition, the statements on labels may include other information of the type commonly found on consumer product labels in the relevant jurisdictions or other information specifically relevant to manufactured nano-objects used (see Annex A for examples of sample label statements).

4.2.2 Instructions for use

Advice on handling, maintenance, cleaning, storage or disposal of the product should be based on the properties of the product. Any advice on different handling, maintenance, cleaning, storage, disposal or first aid instructions for the product as a consequence of nano-object content (i.e. that differs from normal practice or advice for similar products that do not contain manufactured nano-objects) should be provided, if applicable. This information may be provided on the label. Alternatively, the information may be contained in instructions included with the product, attached to the product or affixed to the packaging in such a manner that is ordinarily sold to or used or purchased by consumers.

4.2.3 Emergency and first aid procedures

Emergency and first aid procedures should be based on the properties of the product. In determining this advice, it should be considered whether properties change as a result of nano-object content and thus whether any difference is advised in normal emergency response and first aid procedures when compared with products having the same composition but not containing manufactured nano-objects. This would be relevant in the event of accidental exposure or injury or in respect of action to be taken in the event of an emergency.

5 Obtaining information from other sources

The communication between the companies in the supply chain is the basis for supporting the responsibility of putting labels on the product and the reliability of the labelling (i.e. the information provided on the label). For example, manufactured nano-objects and PCMNOs can enter at one or more points into a more or less complex supply chain from primary manufacturers through to wholesale and retail distributors. In this situation, the downstream business that puts PCMNOs on the marketplace should make reasonable effort to obtain from other sources (e.g. suppliers, scientific literature) information relevant to labelling under this guidance. This guidance does not replace the need to examine existing legal requirements when preparing labels and labelling should not conflict with legal requirements for product labels and labelling established for a particular country or region.

6 Format of label

6.1 General

The information in Clause 4 should be given in such a way that it is visible, legible and identifiable by consumers, on labels permanently attached to the product itself or (where that is impractical) on packaging in which the product is intended to be kept by the consumer.

In recognition of the diversity of regions in which this document might be used, and to further reflect the goal of clear communication to consumers, consideration should be given to providing the information in Clause 4 in the official language of the region in which the PCMNO will be sold.

6.2 Placing of information

The labelling on a product subject to the scope of this Technical Specification should be visible, legible and durable prior to sale to consumers. For example, where the immediate container is enclosed in an outer container or wrapper through which the labelling cannot be read, the label should also be on such outer container or wrapper.

Annex A
(informative)

Examples

Examples of labelling are as follows:

— this product contains manufactured nano-objects;

— ingredient (nano); or, (nano) ingredient;

— contains a manufactured nanoscale form of ingredient;

— contains 0,1 g of nanoscale ingredient;

— contains a dispersion of manufactured nanoscale form of ingredient in (chemical substance Y);

— product should be stored in manner X and correctly disposed of in the manner Y.

Bibliography

[1] ISO 10377, *Consumer product safety — Guidelines for suppliers*

[2] ISO 20282-1, *Ease of operation of everyday products — Part 1: Design requirements for context of use and user characteristics*

[3] ISO/TS 27687:2008, *Nanotechnologies — Terminology and definitions for nano-objects — Nanoparticle, nanofibre and nanoplate*

[4] ISO/TS 80004-4, *Nanotechnologies — Vocabulary — Part 4: Nanostructured materials*

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