St Mary's University College Twickenham London

Products, Privacy & People: Regulating at the Nanoscale
House of Lords, London, 28 Feb 2011

The Labelling 'Nano-products' - update February 2011

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No current legislation and regulation of nanotechnologies in food and packaging applications , except cosmetics in EU

	USA		UK/EC	
	Regulatory Body	Key Legislation/code of practice	Regulatory Body	Key Legislation/Code of practice
Nano-specific legal prescription	None	None	None	**Yes for cosmetics;** none for food and packaging
Relevant legal prescription for nanotechnology and cosmetics	Food and Drug Administration, Environmental Protection Agency	Food, Drug, and Cosmetic Act, 21. U.S.C § 301 (1938), Toxic Substances Control Act (General Approach to Oversight of Nanoscale Materials)	Department of Health, BIS, and Defra / Commission and European Chemicals Agency (ECHA),	**Regulation (EC) No: 1223/2009 30 Nov 2009 *** and Council Directive 76/768/EEC Cosmetics Directive, 1976 O.J. (L262) 169 EU; Cosmetic Products (Safety) regulations, 2003, S.I. 2003/835
Relevant legal prescription for nanotechnology and food applications	Food and Drug Administration, Environmental Protection Agency	Food, Drug, and Cosmetic Act, 21. U.S.C. § 301 (1938), Toxic Substances Control Act (General Approach to Oversight of Nanoscale Materials)	Food Standards Agency (UK) / European Food Safety Authority (EFSA)	Regulation (EC) Nº 258/97 (Novel Food Regulation); Regulation (EC) Nº 882/2004 on Official Feed and Food Controls, 2004 O.J. (L191(1 (EU); Food Safety Act, 1990, c.16; Food Standards Act, 1999, c.28

***requires an element of duty of care and notification of identity, intended use and concentration, characteristics, toxicology profile, MSDS and foreseeable exposure.**

Source: Prof Gary Stevens, GnoSys UK, COSTFA0904 Conference, SMUC, 2010

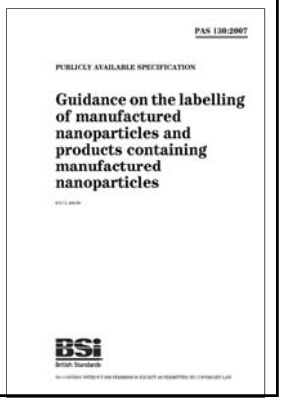
Labelling: from BSI to CEN to ISO

BSI-PAS130

Published 2007

Valid until end-2009

nearly 1,000 downloads


PAS 130:2007

PUBLICLY AVAILABLE SPECIFICATION

Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles

BSi British Standards

CEN and ISO

- ISO/TC 229 and CEN352 Nanotechnologies
- Vienna Agreement / WG2-PG1-TS 13830
- **"Guidance on the labelling of manufactured nano-objects and products containing manufactured nano-objects" (10 page document)**
- Some elements from penultimate draft follow..

Scope

It is voluntary, but normative, guidance

This TS does not substitute for labelling that is required by laws, including those for labelling or pre-market authorization, that are established by competent national authorities.

Does not apply to nano-objects that are …

- produced by **natural** processes (e.g. volcanic) and which are not subjected to further processing.
- are **incidental** (e.g. diesel combustion and similar environmental contaminants)
- The term **'manufactured'** includes natural materials that have been processed.

Definitions

- **nano-object**
  Material with one, two or three external dimensions in the nanoscale. Generic term for all discrete nanoscale objects
- **nanoscale**
  size range from approximately 1 nm to 100 nm
- **product containing manufactured nano-objects (PCMNO)**
  product in which MNOs are deliberately added, mixed, attached, embedded or suspended
- **Nanoscale phenomenon**
  effect attributable to nano-objects or nanoscale regions.

Etc…

Labelling of what?

- MNOs.
- PCMNOs, except where the nano-objects are bound and could not be released ..
- PCMNOs which are components of complex systems (e.g. a vehicle, mobile phone or game console), which could be expected to release MNOs ..
- MNOs and PCMNOs in which there is a significant level of incidental NOs generated that might be released…

Use of the prefix "nano"

The prefix "nano" should only be used in product labelling if either or both…

- the product does contain MNOs, including their agglomerates or aggregates;
- the product displays **nanoscale phenomena** according to the definition

Label statements

Where a nanoscale form of a chemical substance is used the minimum statement should consist of the term 'nanoscale' or 'nano' before or after that substance.

In addition the label statements may include:

- CA number [chemical abstract - ACS]
- Size range
- Specific surface area
- Aspect ratio
- Amount

Examples

- X (nano) [Where 'X' is the chemical substance]
- Contains a manufactured nanoscale form of X;
- Contains 0.1 g of nanoscale X;
- Contains a dispersion of manufactured nanoscale form of X in Y [chemical substance];
- Contains X, approximate size range P nm – Q nm, specific surface area R $m^2 g^{-1}$;
- Contains carbon nanotubes, with an aspect ratio of 1:20.

Other specific information

- Consideration should be given, where relevant, to the inclusion of other specific information about the MNOs used such as:
- Whether free or not, i.e. whether bound in a solid matrix;
- Whether a mixture of MNOs (e.g. Contains nano-objects of both TiO_2 and ZnO);
- Any special disposal requirements (e.g. "Return to…", "Do not burn…", "Do not flush into public waste water system");
- The specific source of the MNOs (e.g. derived from clay);
- Description of the function(s) of MNOs (e.g. use of the material in nano-object form ensures more complete dissolution and hence faster assimilation);
- Packaging information (e.g. for safe opening);
- Date information regarding the MNOs (e.g. normal practice);
- If unstable under specific conditions (e.g. UV, friction);

Annex: *conceptual framework*

Divergent regional needs and interests, hence

- CSR and governance
- supply chain communication
- the precautionary principle
- product stewardship
- life-cycle approach

The ISO Guidance: Conflict & Consensus

- **2011: The final consensus-based draft failed in the international ballot**
- **48%** in favour; CEN got **66%** of the weighted voting, as opposed to the **71%** necessary for approval. What next?
- Economic ideology
  – Market or stakeholders?
- Stakeholder ideology
  – Producers or consumers?

REGULATION: THE FUTURE

EU cosmetics regulation has established the principle of special regulation

More is likely to follow, probably food and food packaging next, followed by amendments to REACH (chemicals)

Life Cycle approach is now widely accepted and will probably be part of any general regulatory framework

Regulation will probably be based on special characteristics in hazard assessment; including size, aspect ratio, surface area and chemistry

Migration out of media, biological transport mechanism, and transformation are critical aspects in exposure assessment – pulmonary, dermal, GE

Bioaccumulation and persistence will be key issues in the risk assessment

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Thank you!

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ADDITIONAL MATERIAL

Precautionary principle

- **The precautionary principle is the concept that lack of scientific evidence of risk should not prevent appropriate precautionary actions being taken.**
- These should be proportionate, non-discriminatory, and consistent with previous action, considering both costs and benefits and be subject to review [8].
- The exercise of "precaution" will necessarily vary depending on the products or sectors regulated, differences in regulatory objectives, and perceived level of risk.
- While the definition notes that costs and benefits should be considered, it does not provide that measures should be cost effective.
- It is recognized that the TS will be usable in countries that do not subscribe to this concept.

Communication

- **Supply Chain communication**
  MNOs may 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 upstream business should inform those downstream when they are in possession of relevant information, and those downstream have a reciprocal duty to ask for any such information, in so far as it is significant for labelling.
- **Unexpected effects**
  Consumers using PCMNOs for the first time may not be prepared for any greater effectiveness, efficiency, capability or other difference compared to similar products that do not contain MNOs. Consumers should therefore be informed or reminded in the instructions for use of effects that may be different from those expected. This may be useful for making the user aware both of the benefits of appropriate use and the possible harms of inappropriate use.