INTERNORM

Negotiating standards for nanotechnologies

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Major obstacles to effective European standardisation

1. Poor Integration with EU research
2. Insufficiently pro-active government support
3. Ineffective 'lay' representation
4. Corporate predominance / bias
5. Poor dissemination
6. Poor funding structure
7. Inadequate administrative processes & structures
8. Ignorance of standards in academic research
9. Inefficient implementation of agreed standards
10. Dilatory implementation of reforms

Conflict & Consensus

General Economic ideology :
Market
and/or
Regulation?

Officiating body:
CEN
and/or
ISO ?

Stakeholders' ideology:
Producers
and/or
Consumers?

CEN/Regulation/consumers
or
ISO/Market/producers

Democratic Deficit

A symptom

- Should the labelling standard embrace business-to-business transactions or only the consumer reception of the products?
- The most recent development is that the former has been dropped from the project, and work continues with a focus only on labelling for consumers
- This restriction perpetuates a democratic deficit

Nanotech consumer products

Over **1,000 consumer products** according to:
Woodrow Wilson International Center for Scholars, Washington DC.

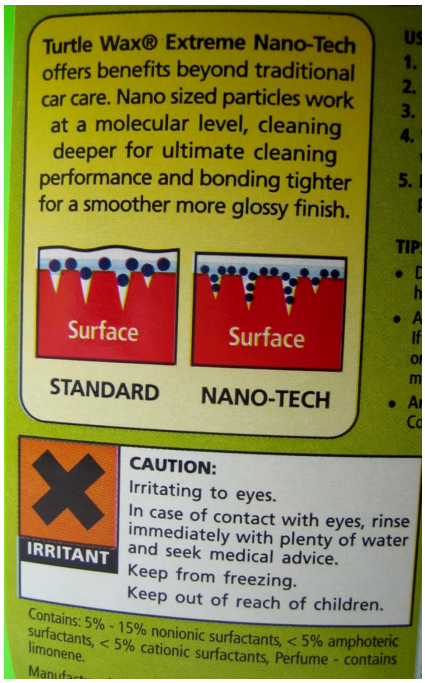
A Nanotechnology Consumer Products Inventory, 2010.

See http://www.nanotechproject.org/44

Label does not say what is the chemical substance of the particles. It only mentions the surfactants.

It provides no other info about the particles (such as size/weight).

It is made in UK by the USA company TurtleWax



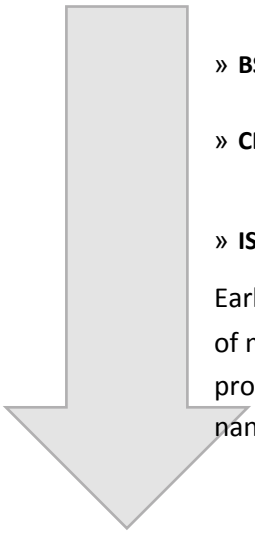
Labelling requirements?

- Currently **no labelling requirements** that specifically address the use of manufactured nano-objects (MNOs) or products containing manufactured nano-objects (PCMNOs), or other regulation specific to the nanoscale properties of nano-objects, other than …
- the requirements imposed by the **Global Harmonized System** (GHS) for classification and labelling of chemicals (including nanomaterials), that provides users with information on the potential hazards.
- the exception of the EU **Cosmetics Regulation** of 2009, which contains a labelling requirement, and there are sectoral labelling and safety requirements that may be relevant to nanotechnology.

ISO Procedure

- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is **approved by 2/3** of the members of the committee casting a vote.
- An ISO/TS is **reviewed after three years** in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.
- If the ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an **International Standard** or be withdrawn.

From BSI to CEN to ISO



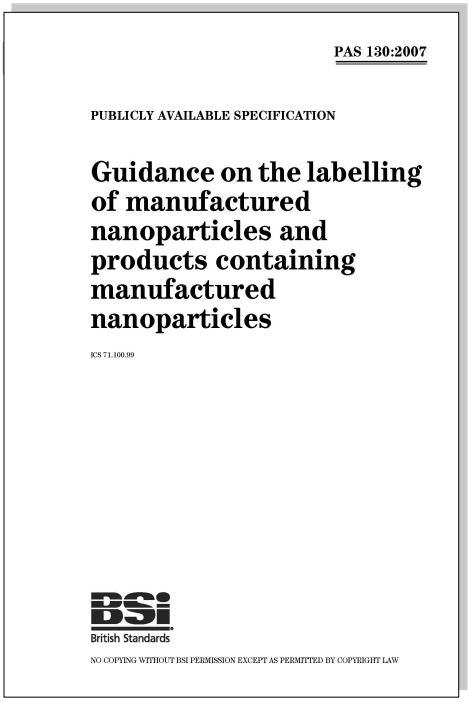
» **BSI: PAS130**

» **CEN: CEN352 Nanotechnologies / WG2-PG1-TS 13830**

» **ISO/TC 229**

Earlier title: "Guidance on the labelling of manufactured nano-objects and products containing manufactured nano-objects" (10 page document)

BSI PAS 130



PAS 130:2007

PUBLICLY AVAILABLE SPECIFICATION

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

ICS 71.100.99

BSi
British Standards

Contents

of the draft guidance of 2011, since amended

- Foreword
- Introduction
- Scope
- Normative References
- Terms and definitions
- Labelling of what?
- Use of the prefix “nano”
- General
- Information for purchase
- Information for use
- Information after purchase
- Form of Labelling
- Labelling statements
- Annex A (informative) Conceptual Framework
- Bibliography

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.

Proposed 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);

CONCLUSION
Controversial questions

- **Social control** of technology?
  - Who decides and how?
- Should the institution of standardisation be **reformed**?
- **GMO** and labelling? Is there a parallel with nano?
- Should nano-labelling be **mandatory**?
- Should labelling following the entire **life-cycle**?

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Merci beaucoup!
Thank you!

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