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Nanomaterials and nanotechnology-based products – Guide to regulation and standards

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Foreword

This PAS was commissioned by the UK Department for Business, Innovation & Skills (BIS). Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 31 October 2013.

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- Applied Nanodetectors
- Chemical Industries Association
- GlaxoSmithKline
- Health and Safety Executive
- Health and Safety Laboratory
- Institute of Nanotechnology
- Institute of Occupational Medicine
- Materials Knowledge Transfer Network
- Nanotechnology Knowledge Transfer Network
- Sustainable Places Research Institute (formerly The ESRC Centre for Business Relationships, Accountability, Sustainability and Society), Cardiff University

Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

The PAS process enables a guide to be rapidly developed in order to fulfil an immediate need in industry. A PAS may be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Use of this document

It has been assumed in the preparation of this PAS that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its recommendations are expressed in sentences in which the principal auxiliary verb is "should".

Commentary, explanation and general informative material is presented in italic type, and does not constitute a normative element. The word "may" is used to express permissibility, e.g. as an alternative to the primary recommendation of the clause. The word "can" is used to express possibility, e.g. a consequence of an action or an event.

Spelling conforms to *The Shorter Oxford English Dictionary* [1]. If a word has more than one spelling, the first spelling in the dictionary is used.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a PAS cannot confer immunity from legal obligations.

0 Introduction

0.1 What does this guide cover?

This PAS documents the present state of UK regulation and standards in the absence of a comprehensive or integrated approach to the control of nanomaterials and nanotechnology-based products. Its aim is to guide companies in understanding regulations and standards applicable to nanomaterials and nanotechnology-based products in a context in which there is usually no mention of or reference to nanotechnologies. In so doing it covers many fields of regulation and standards including environmental protection, occupational health and safety, consumer protection, product safety and liability, and the management of hazardous substances.

Please note that while the PAS tries to provide an overview of applicable regulation and standards it is not intended to provide legal advice on or interpretation of a regulation and how this might be addressed. This PAS should not be taken to constitute advice on particular business dealings or activities and businesses should take their own legal advice as appropriate in such circumstances.

0.2 Why is there a need for this guide?

The use of nanomaterials and nanotechnology-based products for applications relating to certain sectors, such as food and pharmaceuticals, will be subject to the already existing strict regulations that apply to these sectors. How far the use of nanomaterials and nanotechnology-based products for other applications might be covered by existing regulation at different stages of the product life cycle remains the source of much uncertainty, thanks mainly to knowledge gaps (Frater et al. 2006 [2]). These gaps concern the potential toxicity and behaviour of nanomaterials at different stages of their life cycle (including environmental fate) and what measures to used to manage any unanticipated risks (Frater et al. 2006 [2], Aitken et al. 2006 [3] and Uskokovic 2007 [4]). Research conducted in June 2009 by Applied Nanodetectors (see **0.3**), which was funded by the Department for Business, Innovation & Skills (BIS), suggests that these regulatory uncertainties present particular problems for small and medium sized enterprises (SMEs).

With such considerations in mind, the United Kingdom Government [5] and the European Union [6] have stressed that nanotechnology companies have a social responsibility to adhere fully to relevant regulations. Industry is also charged with playing its part in proactively anticipating and managing risks. Important components of any risk management strategy include the sharing of data with peers and regulators, life cycle understandings of products, and communication by industry with external stakeholders, including the public. This was emphasized in a report produced by the House of Lords Select Committee on Science and Technology on nanotechnology and food (House of Lords Select Committee on Science and Technology 2010 [7]).

There is no doubt that the growing pervasiveness of nanomaterials and nanotechnology-based products will present challenges for a raft of regulations, requiring more regulatory integration, and a growing readiness to adopt life-cycle approaches to risk assessment and management.

0.3 Who is this guide for?

With an increasing number of new nanomaterials and nanotechnology-based products becoming available on the EU market, many companies are planning to capitalize on the enhanced properties that these products can offer. However, small companies that want to enter the nanotechnology market face many challenges in understanding the commercial benefits and also how they can address some of the potential adverse effects of these new materials. Their approach to dealing with the potential risks could have a major impact on their ability to commercialize nanomaterials and nanotechnology-based products.

This guidance has been developed primarily for SMEs, to signpost regulations and standards relevant to the importation and manufacture of nanomaterials and nanotechnology-based products. It might also be of interest to other organizations, including larger corporate entities, and a wide range of stakeholders and the public at large.

This PAS has been designed in accordance with the findings of a research report conducted in June 2009 by Applied Nanodetectors, which was funded by the Department for Business, Innovation & Skills (BIS). The research consisted of face-to-face and telephone interviews and focus group meetings with a range of SMEs involved or interested in commercializing nanomaterials and nanotechnology-based products and meetings with academics and regulators with a knowledge of the regulatory arena. These identified their information needs and provided a basis for the development of the guide.

0.4 Overview of the need for regulation for nanomaterials and nanotechnology

There are a wide number of opportunities but also some potential risks associated with nanomaterials and nanotechnology-based products. One of the most important impacts of nanomaterials and nanotechnology-based products stems from end-of-life disposal and the unknown accumulative effects of these products in the environment. In relation to human health, occupational safety (including the inhalation of nanoparticles) is arguably the greatest source of concern. In addition there are other pathways (e.g. dermal and gastrointestinal) to exposure which might be important in consumer products.

Regulation must always map on to both scientific and social understandings of each risk. The Royal Commission on Environmental Pollution [8] has suggested that there is insufficient research and monitoring of nanomaterials and nanotechnology-based products in relation to toxicology and exposure risks. Risk characterization of novel materials is problematic, primarily because traditional thinking dictates that direct comparisons are drawn with conventional materials. Such analogy can lead to shortfalls in protection as nanomaterials and nanotechnology-based products might behave very differently to their conventional equivalents. Different timescales might arise with regard to safety assessments as first generation life-cycle analysis might not adequately predict the possible consequences arising from subsequent generations.

So regulation will inevitably follow advances in scientific understanding and better processes of risk governance. In the meantime, there is no shortage of regulation governing materials generally, including regulation of their production and of the products in which they are incorporated. These regulations are to be utilized as appropriate to try and ensure responsible innovation and use of nanomaterials and nanotechnology-based products. This is vital in foreclosing risks to the environment and health in order that the many undoubted benefits of nanomaterials and nanotechnology-based products might be realized.

0.5 Overview of existing regulation applicable to nanomaterials and nanotechnology

It might be apparent then that there is little regulation that is specific to nanomaterials and nanotechnology-based products though some regulation in the fields of cosmetics and food has now come out of the European Commission in Brussels. Because nanomaterials and nanotechnology-based products should circulate freely in the European single market, it is likely that much of the regulation will be developed by the European Commission. Thereafter, the UK will generally adopt the requirements of EU law by passing its own legislation. One might expect to see this process repeated for various sectors over the coming years.

In the meantime there is ample UK regulation governing areas in which nanomaterials and nanotechnology-based products could conceivably pose a risk, covering, for example, occupational health, product safety or waste disposal. This PAS offers a guide to this complex array of regulation. It focuses primarily on UK regulation even though the obligations might arise initially out of EU law.

There are different types of EU law. The most common are in the form of directives and regulations. Directives set out aims and objectives to be achieved in a particular area, but often do not specify exactly how such aims or objectives are to be realized. They require EU member states to create national legislation before they are effective. Member States are given a set amount of time in which to "transpose" EU Directives (that is, a set amount of time in which to create national legislation which realizes the aims and objectives of the Directive). Regulations are commonly much more detailed and specific. They are effective without the need for any national legislation (that is, they are law that directly applies in the UK and must be complied with).

If an Act of Parliament is passed by the UK Parliament, then that (primary) legislation cannot be challenged or questioned in the courts, providing, perhaps, that it is compatible with human rights' requirements to which the UK subscribes. This is not true for most secondary legislation such as regulations, the responsibility for which has been delegated to a department of government or some other agency. Regulations (and other statutory instruments) produced by such bodies might be challenged in the courts where, for example, the authority to produce regulations has been exceeded or when procedural requirements are not met. This ability to challenge regulations might be crucial where the scope of a regulation and its

application to nanomaterials and nanotechnology-based products is open to doubt.

Most of the regulation covered in this PAS, whether primary or secondary legislation, will place obligations on companies and contain sanctions for failure to comply with these obligations. Clearly then it is vital to follow the law and to check company procedures to ensure that breaches of legal requirements are avoided. This PAS also refers to guidance. Guidance issued by government departments or regulatory agencies is just that – a guide rather than a law. There is no legal requirement to follow guidance but it will usually be sensible to do so since the guidance will indicate what the regulator regards as good practice. Failure to follow guidance might lead to a breach of the law.

0.6 Overview of standards

Standards are developed by standard setting bodies such as BSI and other European and international organizations in an attempt to codify good practice. In so doing, standards serve many purposes, helping the interoperability of products and allowing them to cross borders. Often standards will be concerned with safety and will focus on assisting business to ensure safe working and safe products.

There are considerable advantages to business in following standards. Products that meet standards will trade more easily. Where the standard seeks to ensure safety, following that standard will reduce liability. This is not only because accidents will be less likely to happen, but also because the courts will take some account of compliance with the standard if an accident does occur. To the extent that standards incorporate good practice, it is less likely that a company will be found to have breached a duty of care where a recognized standard has been followed.

Standards are not law and they do not proceed from democratically elected law making bodies. But law relies heavily on standards and it becomes much easier to regulate once standards are in place. Slowly at both national, European and international level, consensus is being reached over definitions and methods for handling nanomaterials and nanotechnology-based products. The essential tasks for regulation of defining, characterizing, assessing and managing risks associated with nanomaterials and nanotechnology-based products depends on international standardization. This PAS therefore covers standards as well as regulation as the two are now combining to offer an effective and efficient structure for the governance of nanomaterials and nanotechnology-based products.

0.7 Definition and characterization of nanomaterials

In October 2011, the European Commission published Recommendation 2011/696/EU on the definition of nanomaterial [9] though it also contains definitions for particle, agglomerate and aggregate. Nanomaterial is defined in the Recommendation as:

> "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm to 100 nm".

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1% and 50%.

The Recommendation suggests that a material should be considered as falling under the definition where the specific surface area by volume of the material is greater than 60 m^2/cm^3.

As a Recommendation, the definition is not binding in itself but only takes effect when incorporated into legislation. The aim of the Recommendation is to ensure uniformity in definitions within regulatory frameworks. Its focus is on capturing materials which might need to be subject to regulation, which is why it might look different to other definitions such as that in DD ISO 80004-1:2010 (see Table 1) which is more concerned with standardization of terms.

The Recommendation is wide-ranging and makes no reference to the origin of nanomaterials/nanoparticles thereby including natural nanoparticles and those incidentally caused by combustion or other processes. As such it focuses simply on size of substances. The Recommendation makes no assumption of risk, as risk assessment is likely to be one of the tasks of any legislation into which the definition is incorporated. It is deliberately wide in scope, though the legislation might later narrow this by introducing a distinction between for example, engineered and natural nanomaterials in deciding what to regulate under that legislation.

There is an example of this in the only use of the definition, to date, in EU legislation. In May 2012, Biocidal Products Regulation (EU) No 528/2012 was adopted. The regulation is the first to include the new definition, albeit in an amended form that, for example, makes no mention of incidental materials.

Moreover, there is no suggestion of a deviation from the 50% threshold as would be allowed by the Recommendation. The opportunity of specific definitions applicable to certain nanomaterials in biocides in the future is made possible by adopting the following wording in the regulation:

> "The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard, in particular to Recommendation 2011/696/EU. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3)".

Note that the Commission plans to review the definition by December 2014, and the suitability of a 50% limit is likely to be one matter under consideration. There are some exceptions to the size range. Recital 17 of the Recommendation states:

> "Given the special circumstances prevailing in the pharmaceutical sector and the specialized nanostructured systems already in use, the definition in this recommendation should not prejudice the use of the term "nano" when defining certain pharmaceuticals and medical devices".

The USA Food and Drug Administration considers that an upper size range of 1 000 nm is applicable for nanomedicine applications [10].

The detailed characterization of any nanomaterial produced or used by an organization is essential to the risks that it might pose. The European regulation for the registration, evaluation, authorization and restriction of chemicals (REACH, see **A.1.1**) imposes a requirement in Annex II, section 9.1, that a safety data sheet for solid materials provides information on granulometry and specific surface area. For properties to be taken into account when describing granulometry see the European Chemicals Agency (ECHA) guidance on the compilation of safety data sheets (see **A.1.1**).

Also note that guidance on the physico-chemical characterization of engineered nanoscale materials for toxicologic assessment is given in PD ISO 13014:2012.

0.8 Future developments

The European Commission is undertaking a study that might lead to additional information requirements for nanomaterials under REACH. There are also measures that suggest future product specific requirements either in the form of safety assessment and/or labelling including:

- The Biocidal Products Regulation (EU) No 528/2012 demands specific assessment, procedural and labelling requirements for nanomaterials [see further the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013];
- The Waste Electrical and Electronic Equipment (WEEE) Directive No 2012/19 suggests that the Commission evaluates the risks of nanomaterials and thereafter amend relevant rules regarding treatment of materials and components of waste electrical and electronic equipment;
- The Restriction of Hazardous Substances (RoHS) Directive No 2011/65 requires that nanomaterials be examined for inclusion within restrictions at the point at which scientific evidence is available;
- The Food Labelling Regulation (EC) No 1169/2011 requires labelling of ingredients containing nanomaterials;
- The Plastic Food Contact Material Regulation (EC) No 10/2011 places prohibitions and restrictions on food contact materials, including nanomaterials.

In addition, a proposed medical devices regulation currently before the European Parliament seeks unified risk assessment of devices that contain nanoparticles capable of release into the body of the patient. If adopted, this regulation will impose design and labelling requirements on such devices.

Finally note that, while there is no EU registry of nanomaterials, some countries such as France and Norway have introduced national reporting structures, which might place registration and other requirements on companies seeking to export to these markets.

1 Scope

This PAS provides an overview of the regulation and standards applicable to nanomaterials and nanotechnology-based products in the United Kingdom.

In particular it provides:

a) a table of regulation identified as being generally applicable irrespective of products produced and activities conducted (see Clause **3**);

b) a table of regulation identified as being applicable to particular product types (see Clause **4**);

c) a table of regulation identified as being applicable to particular activities (see Clause **5**);

d) a table of standards identified as being applicable to nanotechnologies (see Clause **6**);

e) a table of contact details for organizations that can provide further information about the referenced regulation (see Clause **7**); and

f) annexes giving detailed information that supports the interpretation and understanding of the referenced regulation (see Annexes A to H).

NOTE 1 *Whilst this PAS aims to provide an overview of the applicable regulation and standards, it does not purport to be an exhaustive list of all regulation and standards that are applicable to nanomaterials and nanotechnology-based products. For instance, this PAS does not cover regulation and standards relating to intellectual property rights that might vest in companies in the nanotechnology area. Rather its focus is on the regulation of nanomaterials and nanotechnology-based products in order to ensure safeguards to human health and the environment.*

NOTE 2 *While the PAS tries to provide an overview of applicable regulation and standards it is not intended to provide legal advice on or interpretation of a regulation and how this might be addressed.*

NOTE 3 *Definitions of terms used in the scope are given in Table 1.*

Table 1 – Definition of terms used in the scope

Term	Definition	Source
nanoscale	size range from approximately 1 nm to 100 nm ***NOTE 1*** *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 are considered approximate.* ***NOTE 2*** *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.*	DD ISO 80004-1:2010, **2.1**
nanotechnology	application of scientific knowledge to manipulate and control matter in the nanoscale to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules or with bulk materials ***NOTE*** *Manipulate and control includes material synthesis.*	DD ISO 80004-1:2010, **2.3**