

**PAS 137:2013**

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



Department  
for Business  
Innovation & Skills



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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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- Chemical Industries Association
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- Institute of Nanotechnology
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- 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

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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 It will be withdrawn upon publication of its content in, or as, a British Standard.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 use 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<sup>2</sup>/cm<sup>3</sup>.

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      | <p>size range from approximately 1 nm to 100 nm</p> <p><b>NOTE 1</b> 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.</p> <p><b>NOTE 2</b> 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.</p> | DD ISO 80004-1:2010, 2.1 |
| nanotechnology | <p>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</p> <p><b>NOTE</b> Manipulate and control includes material synthesis.</p>                                                                                                                                                                                                         | DD ISO 80004-1:2010, 2.3 |

Table 1 – Definition of terms used in the scope (*continued*)

| Term                    | Definition                                                                                                                                                                                                                                                                                                                                                                                                                               | Source                                |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| nanomaterial            | material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale<br><i>NOTE This generic term is inclusive of nano-object and nanostructured material.</i>                                                                                                                                                                                                                       | DD ISO 80004-1:2010, 2.4              |
| nanostructured material | material having internal nanostructure or surface nanostructure<br><i>NOTE This definition does not exclude the possibility for a nano-object to have internal structure or surface structure. If external dimension(s) are in the nanoscale, the term nano-object is recommended.</i>                                                                                                                                                   | DD ISO 80004-1:2010, 2.7              |
| nano-object             | material with one, two or three external dimensions in the nanoscale<br><i>NOTE Generic term for all discrete nanoscale objects.</i>                                                                                                                                                                                                                                                                                                     | DD ISO 80004-1:2010, 2.5              |
| regulation (noun)       | rule or directive made and maintained by an authority                                                                                                                                                                                                                                                                                                                                                                                    | Shorter Oxford English Dictionary [1] |
| regulation (mass noun)  | the action or process of regulating or being regulated                                                                                                                                                                                                                                                                                                                                                                                   | Shorter Oxford English Dictionary [1] |
| standard                | document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context<br><i>NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.</i> | ISO/IEC Guide 2:2004, 3.2             |

## 2 How to use this guide

### 2.1 Activities and products

This guide helps an organization identify the regulation and standards that might be applicable to the activities the organization wishes to conduct in relation to nanomaterials and nanotechnology-based products. It also examines how those products themselves are regulated. It cannot claim to be completely comprehensive because, for example, a new application of nanomaterials could fall into an area of regulation not considered here. Moreover, there is general legislation, for example on the sale of supply of goods, that is applicable to all products and not covered here. The guide covers those areas where nanomaterials are being incorporated into products and areas where such application can be foreseen and is debated. It also covers the general law on product safety.

This guide can be used to check if a certain activity is subject to regulation. Whether this is so can depend on the product resulting from these activities. As such, this guide can also be used to check if certain products fall into regulation. These two axes of activities and products are key to using the regulation.

This guide first focuses on identifying areas of regulation that are generally applicable to all organizations involved in nanomaterials or nanotechnology-related products. These are grouped by subject in Clause 3. A user of this guide can review the list to identify whether the regulation is applicable to their organization's activities and products. Annex A provides a summary of each regulation referenced and includes a description of who is covered by the regulation. Annexes C to G provide a more detailed overview of each area of regulation.

This guide then focuses on identifying products that are subject to specific regulation. Clause 4 provides a breakdown of product types selected in accordance with those most commonly regulated. A user of this guide can review the list to identify whether their product falls within one of the regulated product types. Annex B provides a summary of each regulation referenced and Annex H provides a more detailed overview of product-specific regulation.

Finally, Clause 5 groups the regulations already identified in Clause 3 and Clause 4 by activities typically engaged in by organizations involved in nanomaterials and nanotechnology-related products. It focuses on

those activities taken by organizations in the course of the production, circulation and disposal of these products. Not every organization will be involved in all of these activities, but they tend to reflect the life cycle of such products. Again these activities tend to be grouped according to those most heavily regulated. Again, the regulations referenced in Clause 5 are linked through to the summaries in Annex A and Annex B, with more detailed information in Annexes C to H.

### 2.2 Regulation

This guide makes a distinction between types of regulation based on the extent to which regulation is specific to nanomaterials and nanotechnology-based products, or is aimed at particular products, or is of general application.

There are no regulations focusing solely on nanotechnologies. In certain sectors, however, a number of regulations have been updated to include nano-specific provisions. These provisions draw a distinction between conventional materials or processes and those operating at the nano-scale. To date, nano-specific provisions have been adopted in relation to:

- a) food additives; and
- b) cosmetic products.

For example, if a company is a distributor of cosmetic products containing nanomaterials, it is under an obligation under the European regulation for cosmetic products (see B.1.2) before placing that product on the EU market to meet additional notification requirements set out in the regulation and to label the nanomaterial content of the product.

The introduction of similar nano-specific provisions is also currently under consideration at EU level in relation to novel foods, food information to consumers, biocidal products, pesticides and hazardous substances.

A number of sectors are subject to product-specific regulations. Unlike those provisions specifically directed at nanotechnologies, these regulations make no distinction between products containing nanomaterials or produced using nanotechnologies and those that do not. However, these regulations do demand specific action from companies in the relevant sector. They might impose pre-market requirements (such as prior

approval, and labelling) and/or post-market duties (such as product-recall, or take-back schemes).

Product-specific regulations are found in a range of sectors including cosmetics, foodstuffs, detergents, biocidal products, medicinal products, pesticides, fertilizers and electrical equipment. The PAS covers these sectoral regulations but it does not cover regulation on specific foodstuffs or medicinal products, etc. as these are covered by well-established regulations. An inventory of current applications of nanomaterials in consumer products is provided by The Project On Emerging Nanotechnologies at <http://www.nanotechproject.org/inventories/consumer/>.

For products without nano-specific or product-specific regulations there is still a fallback position. For example all consumer products are required to conform to general product safety requirements that products must be safe. These requirements make no distinction between conventional scale materials and those at the nanoscale, they apply equally to both.

Nano- and product-specific regulations tend to deal with the marketing of consumer products and introduce both pre- and postmarket requirements. In addition to these marketing controls, persons responsible for manufacturing or supplying products might also be required to comply with regulations at different stages of the life cycle.

These general requirements might include occupational health and safety (to protect workers), pollution controls (to protect the environment) and waste management responsibilities (to ensure safe and sustainable waste handling).

## 2.3 Standards

This guide provides a brief overview of standards that have been developed specifically for the emerging field of nanotechnology. Clause 6 groups such standards by subject and a user can review the subject of the standard to identify whether it could be of use in relation to their activities and products.

One area of particular importance in the development of standards for nanotechnology is the development of a common set of terms and definition. This is of particular importance in emerging technologies where many concepts are still newly formed and rapidly evolving. As such a concerted effort was made by numerous stakeholders to develop such standards, which are developed on the back of the input of international experts and comments received from public consultations to build consensus in this area.

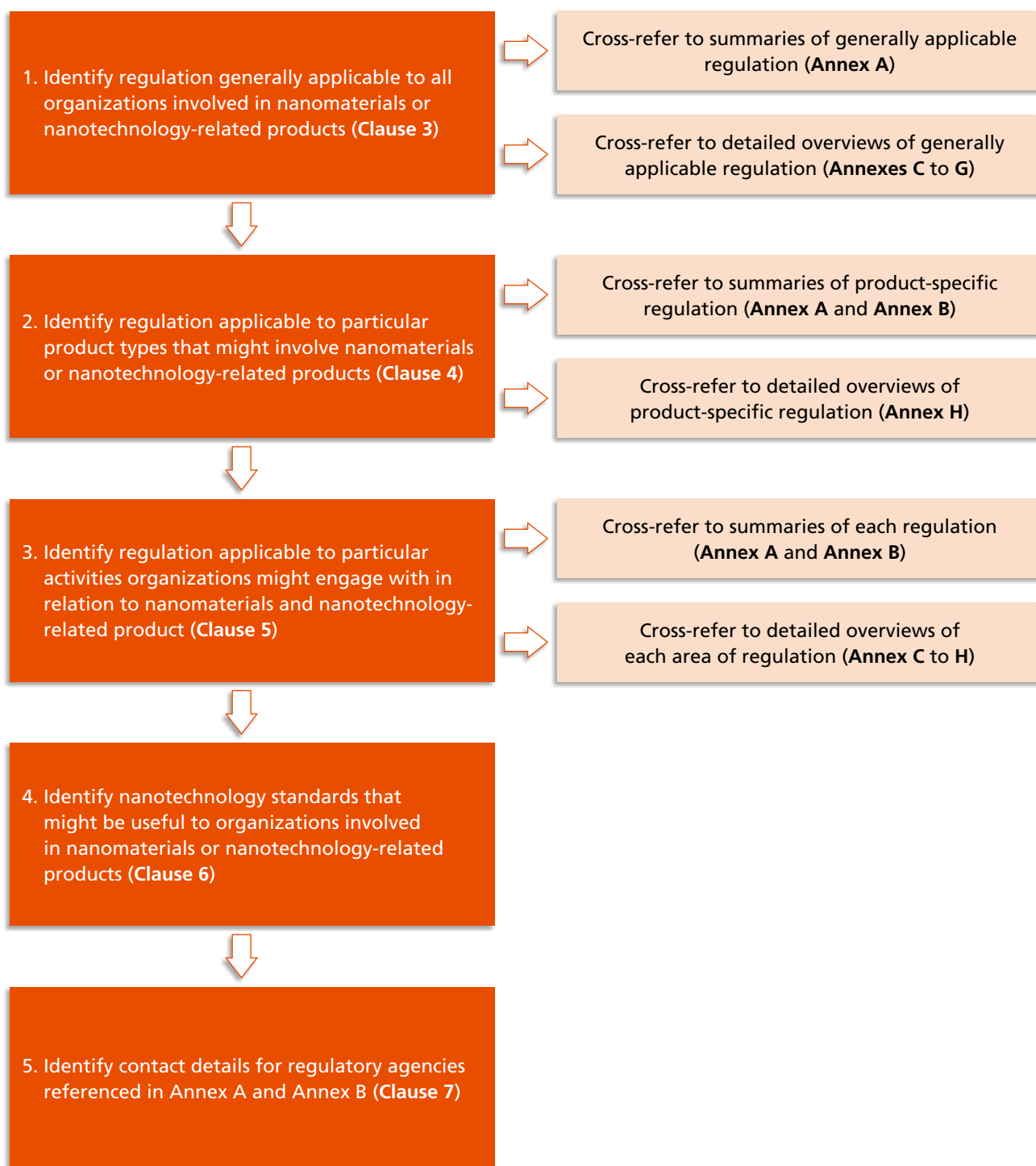
The vocabularies are voluntary, as for most other standards. However, they can be used by industry, regulators, government, academia and others to facilitate communications relating to nanotechnologies. A list of vocabularies relevant to nanotechnologies is included in Clause 6.

## 2.4 Regulatory agencies

Regulation implies that there will be a regulator to whom organizations are answerable. The task of the regulator is first and foremost to assist organizations, especially SMEs, to comply with the requirements of regulation. This being the case, Annex A and Annex B direct organizations to a point of contact in the event of queries. A consolidated list of these contacts is given in Clause 7 alongside a comprehensive set of contact details.

## 2.5 A step-by-step approach to this guide

A step-by-step approach to using this guide is shown in Figure 1.

**Figure 1** – A step-by-step approach to how to use this guide

### 3 Regulation with general applicability

The regulations identified as being generally applicable are grouped by subject in Table 2.

A brief overview of the regulations found under each subject is given in Annex A. The relevant Annex A reference is shown in Table 2.

A more detailed overview of the regulations found under each subject is given in supporting annexes. The relevant annexes are shown in Table 2.

**Table 2** – Regulation with general applicability

| Subject area           | Subject                                                                                   | Summary reference | Detailed reference |
|------------------------|-------------------------------------------------------------------------------------------|-------------------|--------------------|
| Chemical safety        | Registration, evaluation, authorization and restriction of chemicals                      | A.1.1             | Annex C            |
|                        | Chemical hazard information and packaging for supply                                      | A.1.2             | Annex D            |
|                        | Classification, labelling and packaging of substances and mixtures                        | A.1.2             | Annex D            |
|                        | Control of substances hazardous to health                                                 | A.1.3             | Annex D            |
|                        | Dangerous substances and explosive atmospheres                                            | A.1.4             | Annex D            |
| Health and safety      | Health and safety at work                                                                 | A.1.5             | Annex E            |
|                        | Workplace health, safety and welfare                                                      | A.1.6             | Annex E            |
|                        | Reporting of industrial injuries and disease                                              | A.1.7             | Annex E            |
|                        | Protective equipment for employees                                                        | A.1.8             | Annex E            |
|                        | Management of health and safety at work                                                   | A.1.9             | Annex E            |
| Consumer safety        | Product safety                                                                            | A.1.10            | Annex F            |
|                        | Consumer protection                                                                       | A.1.11            | Annex F            |
| Environment protection | Environmental permitting (England and Wales) – Discharge of listed substances             | A.1.12            | Annex G            |
|                        | Environmental permitting (England and Wales) – Discharge trade effluent and water quality | A.1.13            | Annex G            |
|                        | Environmental permitting (England and Wales) – Regulated activities                       | A.1.14            | Annex G            |
|                        | Pollution prevention and control permits (Northern Ireland and Scotland)                  | A.1.15            | Annex G            |
|                        | Waste management licences (Northern Ireland and Scotland)                                 | A.1.16            | Annex G            |

**Table 2** – Regulation with general applicability (*continued*)

| Subject area                                   | Subject                                         | Summary reference | Detailed reference |
|------------------------------------------------|-------------------------------------------------|-------------------|--------------------|
| Environment protection<br>( <i>continued</i> ) | Environmental damage prevention and remediation | A.1.17            | Annex G            |
|                                                | Environmental protection – Waste duty of care   | A.1.18            | Annex G            |
|                                                | Hazardous waste                                 | A.1.19            | Annex H            |
|                                                | Packaging waste                                 | A.1.20            | Annex H            |
|                                                | End-of-life vehicles (ELV)                      | A.1.21            | Annex H            |
|                                                | Waste electrical and electronic equipment       | A.1.22            | Annex H            |
|                                                | Waste batteries and accumulators                | A.1.23            | Annex H            |

## 4 Regulation applicable to particular product types

The regulations identified as being applicable to particular product types are grouped in Table 3.

A brief overview of the regulations applicable for each product type is given in Annex B. Cross-references to the relevant entries in Annex B are given in Table 3. However, also note that first two product types refer to references in Annex A as the regulations they refer to have general applicability.

A more detailed overview of the regulation applicable for each product type is given in further supporting annexes. Cross-references to the relevant annexes are given in Table 3.

**Table 3** – Regulation applicable to particular product types

| Product type                                    | Subject                                                                      | Summary reference | Detailed reference |
|-------------------------------------------------|------------------------------------------------------------------------------|-------------------|--------------------|
| General artefacts, substances and intermediates | Registration, evaluation, authorization and restriction of chemicals (REACH) | A.1.1             | Annex C            |
| Batteries and accumulators                      | Waste batteries and accumulators                                             | A.1.23            | Annex G            |
| Biocidal products                               | Biocidal products regulations                                                | B.1.1             | Annex H            |
| Cosmetics                                       | Cosmetic products regulations                                                | B.1.2             | Annex H            |
| Detergents                                      | Detergents regulations                                                       | B.1.3             | Annex H            |
| Electrical equipment                            | Electrical equipment (safety) regulations                                    | B.1.4             | Annex H            |
|                                                 | Waste electrical and electronic equipment (WEEE)                             | A.1.22            | Annex G            |
| Fertilizers                                     | Fertilizer regulations (Europe)                                              | B.1.5             | Annex H            |
|                                                 | Fertilizer regulations (UK)                                                  | B.1.6             | Annex H            |
| Food and food contact materials                 | General food regulations                                                     | B.1.7             | Annex H            |
|                                                 | Novel foods and novel food ingredients                                       | B.1.8             | Annex H            |
|                                                 | Food labelling                                                               | B.1.9             | Annex H            |
|                                                 | Genetically modified food                                                    | B.1.10            | Annex H            |
|                                                 | Genetically modified organisms                                               | B.1.11            | Annex H            |

**Table 3** – Regulation applicable to particular product types (*continued*)

| Product type                                            | Subject                                              | Summary reference | Detailed reference |
|---------------------------------------------------------|------------------------------------------------------|-------------------|--------------------|
| Food and food contact materials<br>( <i>continued</i> ) | Deliberate release of genetically modified organisms | B.1.12            | Annex H            |
|                                                         | Food additives                                       | B.1.13            | Annex H            |
|                                                         | Food additives purity criteria                       | B.1.14            | Annex H            |
|                                                         | Food supplements                                     | B.1.15            | Annex H            |
|                                                         | Food flavourings                                     | B.1.16            | Annex H            |
|                                                         | Food enzymes                                         | B.1.17            | Annex H            |
| Medicinal products                                      | Marketing authorization                              | B.1.18            | Annex H            |
|                                                         | Parallel import licence                              | B.1.19            | Annex H            |
|                                                         | Manufacturer's and wholesale dealer's licence        | B.1.20            | Annex H            |
| Pesticides                                              | Control of pesticides regulations (COPR)             | B.1.21            | Annex H            |
| Plant protection products                               | Plant protection product regulations                 | B.1.22            | Annex H            |
| Vehicles                                                | End-of-life vehicles (ELV)                           | A.1.21            | Annex G            |

## 5 Regulation applicable to particular activities

The regulations identified as being applicable to particular activities are grouped in Table 4.

A brief overview of the regulations applicable for each activity is given in Annex A and Annex B. Cross-references to the relevant entries in Annex A and Annex B are given in Table 4.

A more detailed overview of the regulations applicable for each activity is given in further supporting annexes. Cross-references to the relevant annexes are given in Table 4.

**Table 4** – Regulation applicable to particular activity

| Activity                 | Subject                                                                      | Summary reference | Detailed reference |
|--------------------------|------------------------------------------------------------------------------|-------------------|--------------------|
| Research and development | Registration, evaluation, authorization and restriction of chemicals (REACH) | A.1.1             | Annex C            |
|                          | Health and safety at work                                                    | A.1.5 to A.1.9    | Annex E            |
|                          | Hazardous materials                                                          | A.1.2 to A.1.4    | Annex D            |
|                          | Chemicals research and usage                                                 | A.1.1             | Annex C            |
|                          | Biocidal products                                                            | B.1.1             | Annex H            |
| Manufacturing            | Health and safety at work                                                    | A.1.5 to A.1.9    | Annex E            |
|                          | Hazardous materials                                                          | A.1.2 to A.1.4    | Annex D            |
|                          | Chemical usage                                                               | A.1.1<br>B.1.1    | Annex C<br>Annex H |
|                          | Environmental controls                                                       | A.1.12 to A.1.17  | Annex G            |
|                          | Risk assessment                                                              | A.1.1<br>A.1.3    | Annex C<br>Annex D |
|                          | Regulatory approvals                                                         | B.1.3 to B.1.6    | Annex H            |
|                          | Licensing of manufacture                                                     | B.1.21            | Annex H            |

Table 4 – Regulation applicable to particular activity (*continued*)

| Activity                                                                | Subject                                       | Summary reference                                     | Detailed reference |
|-------------------------------------------------------------------------|-----------------------------------------------|-------------------------------------------------------|--------------------|
| Introduction to the market/sale (includes importation and registration) | Product authorization                         | A.1.1<br>B.1.2<br>B.1.6<br>B.1.16<br>B.1.19 to B.1.20 | Annex C<br>Annex H |
|                                                                         | Food authorization                            | B.1.10 to B.1.17                                      | Annex H            |
|                                                                         | Medicinal product authorization               | B.1.18                                                | Annex H            |
|                                                                         | Notification of marketing                     | B.1.2,<br>B.1.3                                       | Annex H            |
|                                                                         | Licensing of supply                           | B.1.18 to B.1.19                                      | Annex H            |
|                                                                         | Keeping records of supply                     | B.1.8<br>B.1.10<br>B.1.12<br>B.1.20                   | Annex H            |
|                                                                         | Importation                                   | A.1.11<br>B.1.18 to B.1.19                            | Annex F<br>Annex H |
|                                                                         | Chemicals importation                         | A.1.1<br>B.1.1                                        | Annex C<br>Annex H |
|                                                                         | Product safety                                | A.1.10                                                | Annex F            |
| Packaging and labelling (includes customer information)                 | Hazard identification                         | A.1.2                                                 | Annex D            |
|                                                                         | Labelling                                     | B.1.2 to B.1.6                                        | Annex H            |
|                                                                         | Food labelling                                | B.1.9 to B.1.17                                       | Annex H            |
| Consumer safety                                                         | Product safety and liability                  | A.1.10<br>A.1.11                                      | Annex F            |
| End of life                                                             | Waste disposal, reuse, recovery and recycling | A.1.14<br>A.1.16<br>A.1.18 to A.1.23                  | Annex G            |

## 6 Standards applicable to nanotechnologies

The standards identified as being applicable to nanotechnologies are grouped by subject in Table 5.

UK input into the development of these standards is coordinated by the UK National Standards Body, BSI, through BSI Technical Committee NTI/1, Nanotechnologies. More information on the work of NTI/1 is given on the BSI nanotechnology website.

**Table 5** – Standards applicable to nanotechnologies

| Subject area     | Standard identifier and title                                                                                                                                                     |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Characterization | DD ISO/TS 10798, Nanotechnologies – Characterization of single-wall carbon nanotubes using scanning electron microscopy and energy dispersive X-ray spectrometry analysis         |
|                  | DD ISO/TS 10867, Nanotechnologies – Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy                                           |
|                  | DD ISO/TS 10868, Nanotechnologies – Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy                 |
|                  | DD ISO/TS 11251, Nanotechnologies – Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry |
|                  | DD ISO/TS 11308, Nanotechnologies – Characterization of single-wall carbon nanotubes using thermogravimetric analysis                                                             |
|                  | DD ISO/TS 11888, Nanotechnologies – Characterization of multiwall carbon nanotubes – Mesoscopic shape factors                                                                     |
|                  | DD ISO/TS 13278, Nanotechnologies – Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry                       |
|                  | PAS 139, Detection and characterization of manufactured nano-objects in complex matrices – Guide                                                                                  |
|                  | PD CEN ISO/TR 11811, Nanotechnologies – Guidance on methods for nano- and microtribology measurements                                                                             |
|                  | PD IEC/TS 62607-2-1, Nanomanufacturing – Key control characteristics – Part 2-1: Carbon nanotube materials – Film resistance                                                      |
|                  | PD IEC/TS 62622, Nanotechnologies – Description, measurement and dimensional quality parameters of artificial gratings                                                            |
|                  | PD ISO/TS 10797, Nanotechnologies – Characterization of single-wall carbon nanotubes using transmission electron microscopy                                                       |
|                  | PD ISO/TR 10929, Nanotechnologies – Characterization of multiwall carbon nanotube (MWCNT) samples                                                                                 |

Table 5 – Standards applicable to nanotechnologies (*continued*)

| Subject area                             | Standard identifier and title                                                                                                                   |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Characterization<br>( <i>continued</i> ) | PD ISO/TS 11931, Nanotechnologies – Nanoscale calcium carbonate in powder form – Characteristics and measurement                                |
|                                          | PD ISO/TS 11937, Nanotechnologies – Nanoscale titanium dioxide in powder form - Characteristics and measurement                                 |
|                                          | PD ISO/TS 14101, Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method                      |
|                                          | PD ISO/TR 13014, Nanotechnologies – Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment  |
|                                          | PD ISO/TR 11360, Nanotechnologies – Methodology for the classification and categorization of nanomaterials                                      |
|                                          | PD ISO/TR 14187, Surface chemical analysis – Characterization of nanostructured materials                                                       |
| Classification                           | PD ISO/TR 11360, Nanotechnologies – Methodology for the classification and categorization of nanomaterials                                      |
| Health and safety                        | BS EN ISO 10808, Nanotechnologies – Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing           |
|                                          | BS EN ISO 29701, Nanotechnologies – Endotoxin test on nanomaterial samples for in vitro systems – Limulus amebocyte lysate (LAL) test           |
|                                          | BS EN ISO 10801, Nanotechnologies – Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method |
|                                          | PAS 138, Disposal of manufacturing process waste containing manufactured nano-objects – Guide                                                   |
|                                          | PD 6699-2, Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials                                         |
|                                          | PD 6699-3, Nanotechnologies – Part 3: Guide to assessing airborne exposure in occupational settings relevant to nanomaterials                   |
|                                          | PD ISO/TR 12885, Nanotechnologies – Health and safety practices in occupational settings relevant to nanotechnologies                           |
|                                          | PD ISO/TR 13121, Nanotechnologies – Nanomaterial risk evaluation                                                                                |
|                                          | PD ISO/TR 13329, Nanomaterials – Preparation of Material Safety Data Sheet (MSDS)                                                               |
|                                          | PD ISO/TS 12025, Nanomaterials – Quantification of nano-object release from powders by generation of aerosols                                   |
| Labelling                                | PD ISO/TS 12901-1, Nanotechnologies – Occupational risk management applied to engineered nanomaterials – Part 1: Principles and approaches      |
|                                          | PAS 130, Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles                             |

Table 5 – Standards applicable to nanotechnologies (*continued*)

| Subject area          | Standard identifier and title                                                                                                |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------|
| Product specification | DD ISO/TS 12805, Nanotechnologies – Materials specifications – Guidance on specifying nano-objects                           |
|                       | PD 6699-1, Nanotechnologies – Part 1: Good practice guide for specifying manufactured nanomaterials                          |
| Terminology           | DD ISO/TS 80004-1, Nanotechnologies – Vocabulary – Part 1: Core terms                                                        |
|                       | DD ISO/TS 80004-3, Nanotechnologies – Vocabulary – Part 3: Carbon nano-objects                                               |
|                       | DD ISO/TS 80004-4, Nanotechnologies – Vocabulary – Part 4: Nanostructured materials                                          |
|                       | DD ISO/TS 80004-5, Nanotechnologies – Vocabulary – Part 5: Nano/bio interface                                                |
|                       | DD ISO/TS 80004-7, Nanotechnologies – Vocabulary – Part 7: Diagnostics and therapeutics for healthcare                       |
|                       | DD CEN ISO/TS 27687, Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate |
|                       | PAS 71, Nanoparticles – Vocabulary                                                                                           |
|                       | PAS 131, Terminology for medical, health and personal care applications of nanotechnologies                                  |
|                       | PAS 132, Terminology for the bio-nano interface                                                                              |
|                       | PAS 133, Terminology for nanoscale measurement and instrumentation                                                           |
|                       | PAS 134, Terminology for carbon nanostructures                                                                               |
|                       | PAS 135, Terminology for nanofabrication                                                                                     |
|                       | PAS 136, Terminology for nanomaterials                                                                                       |
|                       | PD ISO/TR 12802, Nanotechnologies – Model taxonomic framework for use in developing vocabularies – Core concepts             |

## 7 Regulatory agencies

Contact details for regulatory agencies responsible for particular areas of regulation are listed alphabetically in Table 6. The agencies included are those referenced in Annex A and Annex B as being the appropriate contact.

**Table 6** – Contact details for regulatory agencies

| Regulatory agency                                                                          | Details                                                                                                                                                                                                      | Description                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Department for Environment, Food and Rural Affairs (Defra) – Customer Contact Unit         | Eastbury House<br>30-34 Albert Embankment<br>London SE1 7TL<br><br>Nobel House<br>17 Smith Square<br>London SW1P 3JR<br>+44 (0)8459 33 55 77<br>helpline@defra.gsi.gov.uk<br>defra.helpline@defra.gsi.gov.uk | Defra is the UK government department responsible for policy and regulations on the environment, food and rural affairs.                                                                                                                                |
| Department for Business Innovation & Skills (BIS) – Cosmetics                              | 1 Victoria Street<br>London SW1H 0ET<br>cosmeticnotification@bis.gsi.gov.uk                                                                                                                                  | BIS is the competent authority in respect of cosmetics regulation under Regulation (EC) No 1223/2009, though the daytoday responsibility for enforcement falls to local authority trading standards departments (see Trading Standards Institute).      |
| Department for Business Innovation & Skills (BIS) – End-of-Life Vehicle Registrations Unit | 1 Victoria Street<br>London SW1H 0ET<br>elvregistration@berr.gsi.gov.uk                                                                                                                                      | BIS is the lead government department for policy relating to ELVs and their disposal. The UK regulations affect the way that certain types of vehicles are designed and how they are treated when they become waste.                                    |
| Department of Health – Customer Service Centre                                             | Richmond House<br>79 Whitehall<br>London SW1A 2NS<br>+44 (0)20 7210 4850                                                                                                                                     | The Department of Health provides strategic leadership for public health, the NHS and social care in England.                                                                                                                                           |
| Environment Agency                                                                         | National Customer Contact Centre<br>PO Box 544<br>Rotherham S60 1BY<br>+44 (0)37 0850 6506<br>enquiries@environment-agency.gov.uk<br>http://www.environment-agency.gov.uk                                    | The Environment Agency is the non-departmental public body responsible for environmental matters in England and Wales.<br><br>The regulator's principle aims are to protect and improve the environment, as well as to promote sustainable development. |

Table 6 – Contact details for regulatory agencies (*continued*)

| Regulatory agency                                                                     | Details                                                                                                                                                                                                                                                          | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| European Chemicals Agency (ECHA)                                                      | PO Box 400<br>00121 Helsinki<br>Finland<br>+35 89 686 180<br><a href="http://echa.europa.eu/home_en.asp">http://echa.europa.eu/home_en.asp</a>                                                                                                                   | The Agency, located in Helsinki, Finland will manage the registration, evaluation, authorization and restriction (REACH) processes for chemical substances to ensure consistency across the European Union. These REACH processes are designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry. However, the first point of contact on REACH should be the relevant national authority, which for the UK is the Health and Safety Executive (HSE). |
| European Commission, Directorate for Health and Consumers                             | B-1049 Brussels<br>Belgium<br>+32 2 299 11 11<br><a href="http://ec.europa.eu/consumers/sectors/cosmetics/cpnf/">http://ec.europa.eu/consumers/sectors/cosmetics/cpnf/</a>                                                                                       | The goal of the Directorate is to make Europe a healthier, safer place, where consumers can be confident that their interests are protected. This Directorate operates the Cosmetic Products Notification Portal (CPNP).                                                                                                                                                                                                                                                                                                            |
| European Food Safety Authority (EFSA)                                                 | Via Carlo Magno 1A<br>43126 Parma<br>Italy<br>+39 0521 036 111<br><a href="http://www.efsa.europa.eu/">http://www.efsa.europa.eu/</a>                                                                                                                            | EFSA undertakes risk assessment regarding food and feed safety in collaboration with national authorities. It provides independent scientific advice and communication on existing and emerging risks.                                                                                                                                                                                                                                                                                                                              |
| European Medicines Agency                                                             | 7 Westferry Circus<br>Canary Wharf<br>London E14 4HB<br>United Kingdom<br>+44 (0)20 7418 8400<br><a href="http://www.ema.europa.eu">http://www.ema.europa.eu</a>                                                                                                 | The European Medicines Agency is based in London. The agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union.                                                                                                                                                                                                                                                                                                                                         |
| Food Standards Agency (FSA) – General                                                 | Aviation House<br>125 Kingsway<br>London WC2B 6NH<br>+44 (0)20 7276 8829<br><a href="mailto:helpline@foodstandards.gsi.gov.uk">helpline@foodstandards.gsi.gov.uk</a><br><a href="http://www.food.gov.uk/">http://www.food.gov.uk/</a>                            | The FSA is an independent Government department created to protect the public's health and consumer interests in relation to food.<br><br>The FSA provides advice and information to the public and Government on food safety and aims to protect consumers through effective food enforcement and monitoring.                                                                                                                                                                                                                      |
| Food Standards Agency (FSA) – Advisory Committee on Novel Foods and Processes (ACNFP) | ACNFP Secretariat<br>Room 3B Aviation House<br>125 Kingsway<br>London WC2B 6NH<br>+44 (0)20 7276 8595<br><a href="mailto:acnfp@foodstandards.gsi.gov.uk">acnfp@foodstandards.gsi.gov.uk</a><br><a href="http://acnfp.food.gov.uk/">http://acnfp.food.gov.uk/</a> | The ACNFP is a non-statutory, independent body of scientific experts that advises the FSA on any matters relating to novel foods and processes.<br><br>It carries out safety assessments of any novel food or process submitted for approval under the EC novel food regulation.                                                                                                                                                                                                                                                    |

Table 6 – Contact details for regulatory agencies (*continued*)

| Regulatory agency                                                                                                                    | Details                                                                                                                                                                                                                                                          | Description                                                                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Food Standards Agency (FSA)<br>Northern Ireland                                                                                      | 10 A-C Clarendon Road<br>Belfast BT1 3BG<br>+44 (0)28 9041 7700<br>infosani@foodstandards.gsi.gov.uk<br><a href="http://www.food.gov.uk/northernireland/">http://www.food.gov.uk/northernireland/</a>                                                            | The FSA Northern Ireland undertakes the work of the FSA in relation to Northern Ireland.<br><br>Its stated aims are to improve food safety and standards and protect the health of the population in Northern Ireland in relation to food.     |
| Food Standards Agency (FSA)<br>Scotland                                                                                              | 6th Floor<br>St Magnus House<br>25 Guild Street<br>Aberdeen AB11 6NJ<br>+44 (0)1224 285 100<br>scotland@foodstandards.gsi.gov.uk<br><a href="http://www.food.gov.uk/scotland/">http://www.food.gov.uk/scotland/</a>                                              | The FSA Scotland undertakes the work of the FSA in relation to Scotland.<br><br>Its stated aims are to improve food safety and standards and protect the health of the population in Scotland in relation to food.                             |
| Food Standards Agency (FSA) Wales                                                                                                    | 11th Floor<br>South Gate House<br>Wood Street<br>Cardiff CF10 1EW<br>+44 (0)29 2067 8999<br>wales@foodstandards.gsi.gov.uk<br><a href="http://www.food.gov.uk/wales/">http://www.food.gov.uk/wales/</a>                                                          | The FSA Wales undertakes the work of the FSA in relation to Wales.<br><br>Its stated aims are to improve food safety and standards and protect the health of the population in Wales in relation to food.                                      |
| Health and Safety Executive (HSE) – General health and safety issues including the control of substances hazardous to health (COSHH) | Redgrave Court<br>Merton Road<br>Bootle<br>Merseyside L20 7HS<br>+44 (0)300 003 1647<br><a href="http://www.hse.gov.uk/contact/index.htm">http://www.hse.gov.uk/contact/index.htm</a><br><a href="http://www.hse.gov.uk/coshh/">http://www.hse.gov.uk/coshh/</a> | HSE is the national independent watchdog for work-related health, safety and illness.<br><br>It is an independent regulator and acts in the public interest to reduce work-related death and serious injury across Great Britain's workplaces. |

Table 6 – Contact details for regulatory agencies (*continued*)

| Regulatory agency                                                                                                                                 | Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Description                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Health and Safety Executive (HSE) – Chemicals Regulation Directorate (CRD)<br>– Detergents, pesticides, biocides and REACH                        | <b>Detergents and pesticides</b><br>Nobel House<br>17 Smith Square<br>London SW1P 3JR<br>+44 (0)8459 33 55 77<br>pesticides&detergents@defra.gsi.gov.uk<br><a href="http://www.detergents.gov.uk">http://www.detergents.gov.uk</a><br><a href="http://www.pesticides.gov.uk">http://www.pesticides.gov.uk</a><br><b>Biocides</b><br>Redgrave Court<br>Merton Road<br>Bootle<br>Merseyside L20 7HS<br>+44 (0)151 951 3317<br>biocides@hse.gsi.gov.uk<br><a href="http://www.hse.gov.uk/biocides">http://www.hse.gov.uk/biocides</a><br><b>REACH</b><br>ukreachca@hse.gsi.gov.uk<br><a href="http://www.hse.gov.uk/reach">http://www.hse.gov.uk/reach</a> | The HSE Chemicals Regulation Directorate (CRD) is responsible for the regulation of biocides, pesticides and detergents. CRD is also the competent authority for the registration, evaluation, authorization and restriction of chemicals (REACH) regulations (see A.1.1).                                                                                                                  |
| Health and Safety Executive (HSE)<br>– Hazardous Installations Directorate (HID)<br>– Specialised Industries Division<br>– Biological Agents Unit | The Notifications Officer<br>Health and Safety Executive<br>Biological Agents Unit<br>Merton Road<br>Bootle<br>Merseyside L20 7HS<br>notificationofficer@hse.gsi.gov.uk                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | The HSE Hazardous Installations Directorate gives advice on administrative matters relating to the submission of notifications under the Genetically Modified Organisms (Contained Use) Regulations 2000 or COSHH.                                                                                                                                                                          |
| Medicines and Healthcare products Regulatory Agency (MHRA) – Parallel Import Section                                                              | 151 Buckingham Palace Road<br>Victoria<br>London SW1W 9SZ<br>+44 (0)20 3080 7400<br>info@mhra.gsi.gov.uk                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | MHRA is responsible for ensuring that medicines and medical devices work, and are acceptably safe.<br>The Parallel Import Section is responsible for the UK Parallel Import Licensing Scheme, which allows medicinal products authorized in other EU Member States to be marketed in the UK, provided the imported products have no therapeutic difference from the equivalent UK products. |
| Medicines and Healthcare products Regulatory Agency (MHRA) – Process Licensing                                                                    | 151 Buckingham Palace Road<br>Victoria<br>London SW1W 9SZ<br>+44 (0)20 3080 6844<br>pcl@mhra.gsi.gov.uk                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | MHRA is responsible for ensuring that medicines and medical devices work, and are acceptably safe.<br>MHRA is responsible for the administrative activities associated with issuing and maintaining manufacturer's and wholesale dealer's licences.                                                                                                                                         |

Table 6 – Contact details for regulatory agencies (*continued*)

| Regulatory agency                                                                                               | Details                                                                                                                                                                                                                                          | Description                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Medicines and Healthcare products Regulatory Agency (MHRA) – Regulatory Information Service (RIS) for medicines | +44 (0)20 3080 7400<br>ris.na@mhra.gsi.gov.uk<br><a href="http://www.mhra.gov.uk/Contactus/RegulatoryInformationService(RIS)formedicines/index.htm">http://www.mhra.gov.uk/Contactus/RegulatoryInformationService(RIS)formedicines/index.htm</a> | MHRA is responsible for ensuring that medicines and medical devices work, and are acceptably safe.<br><br>The RIS acts as the single main point of contact for the marketing authorization holders of medicines and their representatives.                                                                    |
| Natural England                                                                                                 | Natural England<br>Foundry House<br>3 Millsands<br>Riverside Exchange<br>Sheffield S3 8NH<br>+44 (0)845 600 3078<br>enquiries@naturalengland.org.uk<br><a href="http://www.naturalengland.org.uk/">http://www.naturalengland.org.uk/</a>         | Natural England is an Executive Non-departmental Public Body responsible to the Secretary of State for Environment, Food and Rural Affairs. Their purpose is to protect and improve England's natural environment and encourage people to enjoy and get involved in their surroundings.                       |
| Northern Ireland Environment Agency (NIEA) – General                                                            | Klondyke Building<br>Cromac Avenue<br>Gasworks Business Park<br>Malone Lower<br>Belfast BT7 2JA<br>+44 (0)845 302 0008<br>nieainfo@doeni.gov.uk<br><a href="http://www.doeni.gov.uk/niea/">http://www.doeni.gov.uk/niea/</a>                     | The NIEA advises on, and implements, environmental policy in Northern Ireland. Its stated aims are to protect and conserve Northern Ireland's natural heritage and built environment, to control pollution and to promote the wider appreciation of the environment and promote best environmental practices. |
| Northern Ireland Environment Agency (NIEA) – Industrial Pollution and Radiochemical Inspectorate (IPRI)         | Klondyke Building<br>Cromac Avenue<br>Gasworks Business Park<br>Malone Lower<br>Belfast BT7 2JA<br>+44 (0)28 9056 9299<br>ipri@doeni.gov.uk<br><a href="http://www.doeni.gov.uk/niea/">http://www.doeni.gov.uk/niea/</a>                         | The NIEA IPRI is responsible for controlling the keeping and use of radioactive material and the disposal of radioactive waste.                                                                                                                                                                               |
| Scottish Environment Protection Agency (SEPA)                                                                   | Erskine Court<br>Castle Business Park<br>Stirling FK9 4TR<br>+44 (0)1786 457 700<br><a href="http://www.sepa.org.uk">http://www.sepa.org.uk</a>                                                                                                  | SEPA is Scotland's environmental regulator. Its main role is to protect and improve the environment in Scotland.<br><br>SEPA is a non-departmental public body, accountable through Scottish Ministers to the Scottish Parliament.                                                                            |

Table 6 – Contact details for regulatory agencies (*continued*)

| Regulatory agency                               | Details                                                                                                                                                                                                                         | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trading Standards Institute (TSI)               | 1 Sylvan Court<br>Sylvan Way<br>Southfields Business Park<br>Basildon<br>Essex SS15 6TH<br>+44 (0)845 404 0506<br>productinfo@tsi.org.uk<br><a href="http://www.tradingstandards.gov.uk">http://www.tradingstandards.gov.uk</a> | Trading standards professionals enforce consumer related legislation. TSI influences this through the work of their lead officers, who are trading standards professionals. TSI and their lead officers influence by: <ul style="list-style-type: none"> <li>a) working with the Government and stakeholders;</li> <li>b) responding to consultations with front line knowledge; and</li> <li>c) campaigning on issues raised on behalf of consumers and business.</li> </ul> |
| Vehicles and Operator Services Agency (VOSA)    | The Ellipse<br>Padley Road<br>Swansea SA1 8AN<br>+44 (0)300 123 9000<br>enquiries@vosa.gov.uk<br><a href="http://www.dft.gov.uk/vosa/index.htm">http://www.dft.gov.uk/vosa/index.htm</a>                                        | VOSA provides a range of licensing, testing and enforcement services with the aim of improving the roadworthiness standards of vehicles ensuring the compliance of operators and drivers, and supporting the independent Traffic Commissioners.                                                                                                                                                                                                                               |
| Welsh Government – Department for Public Health | Cathays Park<br>Cardiff CF10 3NQ<br>+44 (0)845 010 3300                                                                                                                                                                         | The department leads on public health strategy and programmes, with the aim of protecting and improving health and reducing health inequalities.                                                                                                                                                                                                                                                                                                                              |

## Annex A (informative)

### Regulation with general applicability

A summary of regulation identified as generally applicable is given in Table A.1.

**Table A.1** – Regulation with general applicability

| Regulation                                                                         | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A.1.1 Registration, evaluation, authorization and restriction of chemicals (REACH) | <p><i>What:</i></p> <p>Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals</p> <p>Enforced in the UK by The REACH Enforcement Regulations 2008</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                                                                    | <p><i>Who:</i></p> <p>Those who manufacture or import substances in quantities greater than one tonne per year. A substance is a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but it excludes any solvent which may be separated without affecting the stability of the substance or changing its composition.</p> <p>There are also limited obligations on “downstream users” of chemicals, being those who use substances but who do not themselves manufacture or import them.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                                                    | <p><i>How:</i></p> <p>Those who manufacture or import chemicals in quantities greater than one tonne per year are obliged to register those chemicals with the European Chemicals Agency (ECHA). Registration requires testing of the intrinsic properties of the substance being registered and transmission of that data to ECHA. The amount of data needed to be submitted for registration (and by what date) varies according to: the volume of substance; and the intrinsic harmfulness of the substance, with high volume, highly harmful substances needing to register first and with a correspondingly higher amount of testing data. Registration requirements are reduced for those substances manufactured or imported for the purposes of scientific research and development. The Health and Safety Executive is the regulatory agency in the UK primarily responsible for REACH enforcement and providing advice to businesses on compliance.</p> <p>Downstream users of chemicals should follow the instructions on safety data sheets available from <a href="http://www.hse.gov.uk/reach/resources/reachsds.pdf">http://www.hse.gov.uk/reach/resources/reachsds.pdf</a>. If the exposition scenarios attached to these sheets fails to cover your utilization of the chemical, you should contact your vendor so that your utilization can be included in an exposition scenario, or it might be necessary to develop your own chemical safety report.</p> <p>You should also contact your vendors where you have new information regarding the risks attached to your use or where you think that the risk management measures are not appropriate. Your customers might need to be informed of hazards and conditions of safe use and appropriate risk management advice for your preparations, if you are a formulator. If you are a producer, customers should be informed where the content of certain very dangerous substances (candidates for authorization under REACH) exceeds a concentration of 0.1% w/w in the articles you produce.</p> |

Table A.1 – Regulation with general applicability (*continued*)

| Regulation                                                                                                                                     | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                | <p><i>Sources of information:</i></p> <ul style="list-style-type: none"> <li>• Annex C, Registration, evaluation, authorization and restriction of chemicals</li> <li>• European Chemicals Agency website</li> <li>• European Commission REACH website</li> <li>• Health and Safety Executive REACH website</li> </ul> <p><i>Useful contacts:</i></p> <ul style="list-style-type: none"> <li>• European Chemicals Agency</li> <li>• Health and Safety Executive – Chemicals Regulation Directorate</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| A.1.2 Chemical hazard information and packaging for supply (CHIP) and classification, labelling and packaging of substances and mixtures (CLP) | <p><i>What:</i></p> <p>The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 Providing for the enforcement of Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006</p> <p><i>Who:</i></p> <p>Suppliers of dangerous chemicals. Suppliers include manufacturers, importers, distributors, wholesalers and retailers. Dangerous chemicals are those which are listed in Table 3.2 of Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 and those which can be classified into certain categories, such as explosive, oxidizing, extremely flammable, carcinogenic, toxic, etc. The full list of categories can be found in Column 1 of Schedule 1 of the CHIP regulations.</p> <p><i>How:</i></p> <p>Those who supply dangerous chemicals are obliged to identify the hazards (dangers) of the chemical. This is known as “classification”, for example, dangerous chemicals might be carcinogenic, irritating or explosive. In addition, suppliers must give information about the hazards to their customers, normally via the packaging of the chemical. Note that on a gradual basis to 2015, the CHIP regulations will be replaced by Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.</p> <p><i>Sources of information:</i></p> <ul style="list-style-type: none"> <li>• Annex D, Hazardous materials</li> <li>• Health and Safety Executive CHIP website</li> <li>• Health and Safety Executive, <i>Approved Classification and Labelling Guide – Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP 4)</i></li> </ul> <p><i>Useful contacts:</i></p> <ul style="list-style-type: none"> <li>• Health and Safety Executive – General health and safety issues</li> </ul> |

Table A.1 – Regulation with general applicability (*continued*)

| Regulation                                              | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A.1.3 Control of substances hazardous to health (COSHH) | <i>What:</i><br>The Control of Substances Hazardous to Health Regulations 2002 (as amended)                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                                         | <i>Who:</i><br>Employers                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|                                                         | <i>How:</i><br>COSHH requires employers to control substances that are hazardous to health by preventing or reducing worker's exposure to such substances.<br>The Health and Safety Executive (HSE) advises that a COSHH assessment should be carried out for all work involving nanomaterials and that "suitable and sufficient risk management measures" are put in place.                                                                                                                        |
|                                                         | <i>Sources of information:</i> <ul style="list-style-type: none"> <li>• Annex D, Hazardous materials</li> <li>• Health and Safety Executive COSHH website</li> <li>• Health and Safety Executive, <i>Using nanomaterials at work - Including carbon nano-tubes (CNTs) and other bio-persistent high aspect ratio nanomaterials (HARNs)</i></li> </ul>                                                                                                                                               |
| A.1.4 Dangerous substances and explosive atmospheres    | <i>Useful contacts:</i> <ul style="list-style-type: none"> <li>• Health and Safety Executive – General health and safety issues</li> </ul>                                                                                                                                                                                                                                                                                                                                                          |
|                                                         | <i>What:</i><br>Dangerous Substances and Explosive Atmospheres Regulations 2002                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                                         | <i>Who:</i><br>Employers                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|                                                         | <i>How:</i><br>Employers must find out what dangerous substances are in their workplace and what the fire and explosion risks are, put control measures in place to either remove those risks or, where this is not possible, control them. The HSE advises that dangerous substances are "substances used or present at work that could, if not properly controlled, cause harm to people as a result of a fire or explosion" and give the examples of solvents, paints, flammable gases and dust. |
|                                                         | <i>Sources of information:</i> <ul style="list-style-type: none"> <li>• Annex D, Hazardous materials</li> <li>• Health and Safety Executive DSEAR website</li> </ul>                                                                                                                                                                                                                                                                                                                                |
|                                                         | <i>Useful contacts:</i> <ul style="list-style-type: none"> <li>• Health and Safety Executive – General health and safety issues</li> </ul>                                                                                                                                                                                                                                                                                                                                                          |

Table A.1 – Regulation with general applicability (*continued*)

| Regulation                                 | Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A.1.5 Health and safety at work            | <p><i>What:</i><br/>Health and Safety at Work etc. Act 1974</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                            | <p><i>Who:</i><br/>All employers</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                            | <p><i>How:</i><br/>Employers are under a variety of duties towards their employees, including to:</p> <ul style="list-style-type: none"> <li>a) provide and maintain safe plant and safe systems of work to avoid risks to health (plant here covering any machinery, equipment or appliances used in the workplace);</li> <li>b) ensure use, handling, storage, transport of articles and substances is safe; and</li> <li>c) provide necessary information, instruction, training and supervision so that employees can carry out their jobs safely.</li> </ul> <p>The employer should devise, keep up to date and publicize to employees a written safety policy together with appropriate arrangements for carrying out the policy.</p> <p>Employers with fewer than five employees do not need to keep a written record of their risk assessments or policies.</p> |
|                                            | <p><i>Sources of information:</i></p> <ul style="list-style-type: none"> <li>• Annex E, Health and safety</li> <li>• Health and Safety Executive HSWA website</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                            | <p><i>Useful contacts:</i></p> <ul style="list-style-type: none"> <li>• Health and Safety Executive – General health and safety issues</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| A.1.6 Workplace health, safety and welfare | <p><i>What:</i><br/>Workplace (Health, Safety and Welfare) Regulations 1992</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                            | <p><i>Who:</i><br/>All employers</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                            | <p><i>How:</i><br/>Employers have obligations in relation to the state and condition of their workplace. This includes obligations relating to maintenance of the property, ventilation, temperature, lighting, cleanliness and the provision of washing and sanitary facilities, among other matters.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                                            | <p><i>Sources of information:</i></p> <ul style="list-style-type: none"> <li>• Annex E, Health and safety</li> <li>• Health and Safety Executive, <i>Workplace health, safety and welfare – A short guide for managers</i></li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|                                            | <p><i>Useful contacts:</i></p> <ul style="list-style-type: none"> <li>• Health and Safety Executive – General health and safety issues</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |