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

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Contents

Foreword

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

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- Applied Nanodetectors
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- Materials Knowledge Transfer Network
- Nanotechnology Knowledge Transfer Network
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Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

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 It will be withdrawn upon publication of its content in, or as, a British Standard.

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

Use of this document

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

Presentational conventions

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

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

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

Contractual and legal considerations

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

Compliance with a PAS cannot confer immunity from legal obligations.

0 Introduction

0.1 What does this guide cover?

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

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

0.2 Why is there a need for this guide?

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

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

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

0.3 Who is this guide for?

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

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

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

0.4 Overview of the need for regulation for nanomaterials and nanotechnology

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

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

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

0.5 Overview of existing regulation applicable to nanomaterials and nanotechnology

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

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

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

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

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

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

0.6 Overview of standards

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

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

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

0.7 Definition and characterization of nanomaterials

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

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

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

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

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

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

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

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

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

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

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

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

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

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

0.8 Future developments

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

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

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

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

1 Scope

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

In particular it provides:

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

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

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

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

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

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

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

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

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

Table 1 – Definition of terms used in the scope

Term	Definition	Source
nanoscale	size range from approximately 1 nm to 100 nm ***NOTE 1*** *Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.* ***NOTE 2*** *The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.*	DD ISO 80004-1:2010, **2.1**
nanotechnology	application of scientific knowledge to manipulate and control matter in the nanoscale to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules or with bulk materials ***NOTE*** *Manipulate and control includes material synthesis.*	DD ISO 80004-1:2010, **2.3**

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 ***NOTE*** *This generic term is inclusive of nano-object and nanostructured material.*	DD ISO 80004-1:2010, **2.4**
nanostructured material	material having internal nanostructure or surface nanostructure ***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.*	DD ISO 80004-1:2010, **2.7**
nano-object	material with one, two or three external dimensions in the nanoscale ***NOTE*** *Generic term for all discrete nanoscale objects.*	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 ***NOTE*** *Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.*	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**.

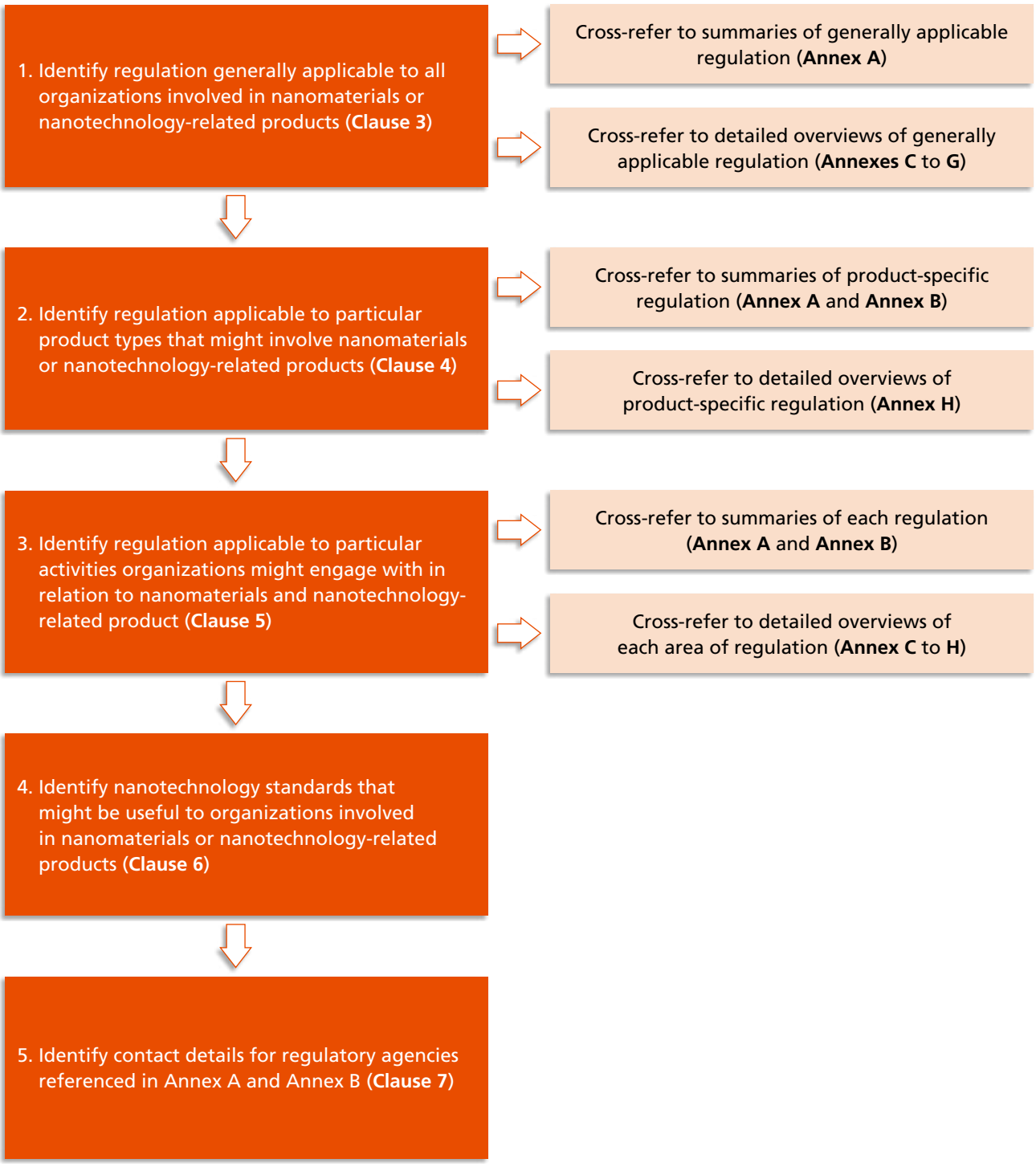
2.4 Regulatory agencies

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 *(continued)*	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 *(continued)*	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 B.1.1	Annex C Annex H
	Environmental controls	A.1.12 to A.1.17	Annex G
	Risk assessment	A.1.1 A.1.3	Annex C 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 B.1.2 B.1.6 B.1.16 B.1.19 to B.1.20	Annex C 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, B.1.3	Annex H
	Licensing of supply	B.1.18 to B.1.19	Annex H
	Keeping records of supply	B.1.8 B.1.10 B.1.12 B.1.20	Annex H
	Importation	A.1.11 B.1.18 to B.1.19	Annex F Annex H
	Chemicals importation	A.1.1 B.1.1	Annex C 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 A.1.11	Annex F
End of life	Waste disposal, reuse, recovery and recycling	A.1.14 A.1.16 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 *(continued)*	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
	PD ISO/TS 12901-1, Nanotechnologies – Occupational risk management applied to engineered nanomaterials – Part 1: Principles and approaches
Labelling	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 30-34 Albert Embankment London SE1 7TL Nobel House 17 Smith Square London SW1P 3JR +44 (0)8459 33 55 77 helpline@defra.gsi.gov.uk 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 London SW1H 0ET 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 London SW1H 0ET 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 79 Whitehall London SW1A 2NS +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 PO Box 544 Rotherham S60 1BY +44 (0)37 0850 6506 enquiries@environment-agency.gov.uk http://www.environment-agency.gov.uk	The Environment Agency is the non-departmental public body responsible for environmental matters in England and Wales. 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 00121 Helsinki Finland +35 89 686 180 http://echa.europa.eu/home_en.asp	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 Belgium +32 2 299 11 11 http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/	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 43126 Parma Italy +39 0521 036 111 http://www.efsa.europa.eu/	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 Canary Wharf London E14 4HB United Kingdom +44 (0)20 7418 8400 http://www.ema.europa.eu	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 125 Kingsway London WC2B 6NH +44 (0)20 7276 8829 helpline@foodstandards.gsi.gov.uk http://www.food.gov.uk/	The FSA is an independent Government department created to protect the public's health and consumer interests in relation to food. The FSA provides advice and information to the public and Government on food safety and aims to protects consumers through effective food enforcement and monitoring.
Food Standards Agency (FSA) –Advisory Committee on Novel Foods and Processes (ACNFP)	ACNFP Secretariat Room 3B Aviation House 125 Kingsway London WC2B 6NH +44 (0)20 7276 8595 acnfp@foodstandards.gsi.gov.uk http://acnfp.food.gov.uk/	The ACNFP is a non-statutory, independent body of scientific experts that advises the FSA on any matters relating to novel foods and processes. 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) Northern Ireland	10 A-C Clarendon Road Belfast BT1 3BG +44 (0)28 9041 7700 infofsani@foodstandards.gsi.gov.uk http://www.food.gov.uk/northernireland/	The FSA Northern Ireland undertakes the work of the FSA in relation to Northern Ireland. 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) Scotland	6th Floor St Magnus House 25 Guild Street Aberdeen AB11 6NJ +44 (0)1224 285 100 scotland@foodstandards.gsi.gov.uk http://www.food.gov.uk/scotland/	The FSA Scotland undertakes the work of the FSA in relation to Scotland. 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 South Gate House Wood Street Cardiff CF10 1EW +44 (0)29 2067 8999 wales@foodstandards.gsi.gov.uk http://www.food.gov.uk/wales/	The FSA Wales undertakes the work of the FSA in relation to Wales. 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 Merton Road Bootle Merseyside L20 7HS +44 (0)300 003 1647 http://www.hse.gov.uk/contact/index.htm http://www.hse.gov.uk/coshh/	HSE is the national independent watchdog for work-related health, safety and illness. 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) – Detergents, pesticides, biocides and REACH	**Detergents and pesticides** Nobel House 17 Smith Square London SW1P 3JR +44 (0)8459 33 55 77 pesticides&detergents@defra.gsi.gov.uk http://www.detergents.gov.uk http://www.pesticides.gov.uk **Biocides** Redgrave Court Merton Road Bootle Merseyside L20 7HS +44 (0)151 951 3317 biocides@hse.gsi.gov.uk http://www.hse.gov.uk/biocides **REACH** ukreachca@hse.gsi.gov.uk http://www.hse.gov.uk/reach	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) – Hazardous Installations Directorate (HID) – Specialised Industries Division – Biological Agents Unit	The Notifications Officer Health and Safety Executive Biological Agents Unit Merton Road Bootle Merseyside L20 7HS 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 Victoria London SW1W 9SZ +44 (0)20 3080 7400 info@mhra.gsi.gov.uk	MHRA is responsible for ensuring that medicines and medical devices work, and are acceptably safe. 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 Victoria London SW1W 9SZ +44 (0)20 3080 6844 pcl@mhra.gsi.gov.uk	MHRA is responsible for ensuring that medicines and medical devices work, and are acceptably safe. 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 ris.na@mhra.gsi.gov.uk http://www.mhra.gov.uk/Contactus/RegulatoryInformationService(RIS)formedicines/index.htm	MHRA is responsible for ensuring that medicines and medical devices work, and are acceptably safe. The RIS acts as the single main point of contact for the marketing authorization holders of medicines and their representatives.
Natural England	Natural England Foundry House 3 Millsands Riverside Exchange Sheffield S3 8NH +44 (0)845 600 3078 enquiries@naturalengland.org.uk http://www.naturalengland.org.uk/	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 Cromac Avenue Gasworks Business Park Malone Lower Belfast BT7 2JA +44 (0)845 302 0008 nieainfo@doeni.gov.uk http://www.doeni.gov.uk/niea/	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 Cromac Avenue Gasworks Business Park Malone Lower Belfast BT7 2JA +44 (0)28 9056 9299 ipri@doeni.gov.uk http://www.doeni.gov.uk/niea/	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 Castle Business Park Stirling FK9 4TR +44 (0)1786 457 700 http://www.sepa.org.uk	SEPA is Scotland's environmental regulator. Its main role is to protect and improve the environment in Scotland. 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 Sylvan Way Southfields Business Park Basildon Essex SS15 6TH +44 (0)845 404 0506 productinfo@tsi.org.uk http://www.tradingstandards.gov.uk	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: a) working with the Government and stakeholders; b) responding to consultations with front line knowledge; and c) campaigning on issues raised on behalf of consumers and business.
Vehicles and Operator Services Agency (VOSA)	The Ellipse Padley Road Swansea SA1 8AN +44 (0)300 123 9000 enquiries@vosa.gov.uk http://www.dft.gov.uk/vosa/index.htm	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 Cardiff CF10 3NQ +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)	*What:* 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 Enforced in the UK by The REACH Enforcement Regulations 2008
	Who: 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. There are also limited obligations on "downstream users" of chemicals, being those who use substances but who do not themselves manufacture or import them.
	How: 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. Downstream users of chemicals should follow the instructions on safety data sheets available from http://www.hse.gov.uk/reach/resources/reachsds.pdf. 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. 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.

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

Regulation	Summary
	Sources of information: • Annex C, Registration, evaluation, authorization and restriction of chemicals • European Chemicals Agency website • European Commission REACH website • Health and Safety Executive REACH website
	Useful contacts: • European Chemicals Agency • Health and Safety Executive – Chemicals Regulation Directorate
A.1.2 Chemical hazard information and packaging for supply (CHIP) and classification, labelling and packaging of substances and mixtures (CLP)	*What:* 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
	Who: 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.
	How: 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.
	Sources of information: • Annex D, Hazardous materials • Health and Safety Executive CHIP website • Health and Safety Executive, *Approved Classification and Labelling Guide – Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP 4)*
	Useful contacts: • Health and Safety Executive – General health and safety issues

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

Regulation	Summary
A.1.3 Control of substances hazardous to health (COSHH)	*What:* The Control of Substances Hazardous to Health Regulations 2002 (as amended)
	Who: Employers
	How: COSHH requires employers to control substances that are hazardous to health by preventing or reducing worker's exposure to such substances. 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.
	Sources of information: • Annex D, Hazardous materials • Health and Safety Executive COSHH website • Health and Safety Executive, *Using nanomaterials at work - Including carbon nano-tubes (CNTs) and other bio-persistent high aspect ratio nanomaterials (HARNs)*
	Useful contacts: • Health and Safety Executive – General health and safety issues
A.1.4 Dangerous substances and explosive atmospheres	*What:* Dangerous Substances and Explosive Atmospheres Regulations 2002
	Who: Employers
	How: 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.
	Sources of information: • Annex D, Hazardous materials • Health and Safety Executive DSEAR website
	Useful contacts: • Health and Safety Executive – General health and safety issues

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

Regulation	Summary
A.1.5 Health and safety at work	*What:* Health and Safety at Work etc. Act 1974
	Who: All employers
	How: Employers are under a variety of duties towards their employees, including to: 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); b) ensure use, handling, storage, transport of articles and substances is safe; and c) provide necessary information, instruction, training and supervision so that employees can carry out their jobs safely. The employer should devise, keep uptodate and publicize to employees a written safety policy together with appropriate arrangements for carrying out the policy. Employers with fewer than five employees do not need to keep a written record of their risk assessments or policies.
	Sources of information: • Annex E, Health and safety • Health and Safety Executive HSWA website
	Useful contacts: • Health and Safety Executive – General health and safety issues
A.1.6 Workplace health, safety and welfare	*What:* Workplace (Health, Safety and Welfare) Regulations 1992
	Who: All employers
	How: 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.
	Sources of information: • Annex E, Health and safety • Health and Safety Executive, *Workplace health, safety and welfare – A short guide for managers*
	Useful contacts: • Health and Safety Executive – General health and safety issues

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

Regulation	Summary
A.1.7 Reporting of industrial injuries and disease	*What:* The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013
	Who: All employers
	How: Employers are obliged to report work-related deaths, major injuries or over-three-day injuries, work related diseases and dangerous occurrences (near miss accidents) to the Health and Safety Executive (HSE). There are varying timescales for when a report is legally required, for example, deaths and major injuries must be reported "without delay", "near misses" need to reported "immediately", while a less serious injury (which results in an employee being absent from work for more than three days) must be reported within ten days. While these are the legal time limits, although it is advisable to contact the HSE as soon as possible.
	Sources of information: • Annex E, Health and safety • Health and Safety Executive RIDDOR website
	Useful contacts: • Health and Safety Executive – General health and safety issues
A.1.8 Protective equipment for employees	*What:* Personal Protective Equipment at Work Regulations 2002
	Who: Employers
	How: Employers have to provide personal protective equipment for employees (for example, safety helmets, gloves, eye protection, high visibility clothing, safety footwear and safety harnesses) wherever there are risks to health and safety that cannot be adequately controlled in other ways. For dermal exposure or ingestion of nanomaterials, the Health and Safety Executive advises that control methods based on personal protective equipment might not be as effective as they are in existing processes. Given this, particular care and specialist advice should be taken.
	Sources of information: • Annex E, Health and safety • Health and Safety Executive, *Personal protective equipment (PPE) at work – A brief guide* • Health and Safety Executive, *Nanoparticles: An occupational hygiene review*
	Useful contacts: • Health and Safety Executive – General health and safety issues

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

Regulation	Summary
A.1.9 Management of health and safety at work	*What:* The Management of Health and Safety at Work Regulations 1999
	Who: All employers
	How: In order to manage health and safety at work, employers must carry out risk assessments. In addition, they must also: a) make arrangements for implementing the health and safety measures in accordance with findings from the risk assessments; b) appoint competent people to help implement the measures; and c) set up emergency procedures. Where there are five or more employees, employers are required to make a record of the significant findings of the risk assessment. The Health and Safety Executive (HSE) views nanomaterials as being substances of very high concern and advises that a precautionary approach should be taken to the risk management of all nanomaterials. If the use of nanomaterials cannot be avoided, the HSE expects a "high level of control" to be used.
	Sources of information: • Annex E, Health and safety • Health and Safety Executive managing for health and safety website • Health and Safety Executive, *Five steps to risk assessment* • Health and Safety Executive, *Using nanomaterials at work - Including carbon nano-tubes (CNTs) and other bio-persistent high aspect ratio nanomaterials (HARNs)*
	Useful contacts: • Health and Safety Executive – General health and safety issues

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

Regulation	Summary
A.1.10 Product safety	*What:* The General Product Safety Regulations 2005 Implementing in the UK Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
	Who: Producers of products. A producer here will include both a manufacturer of the product and also the first importer of the product into the European market. The notion of "producer" can also include someone reconditioning or customizing a product.
	How: Products intended for consumer use shall only be placed on the European market if they are "safe". "Products" here has a wide-ranging definition covering all goods that placed on the market, or supplied or made available to consumers for their private use. "Placing on the market" is a concept wider than sale so that it can include, for example, leasing or hiring out goods. In consequence, any product in circulation intended for consumer use that contains nanomaterials must be safe.
	Sources of information: • Annex F, Consumer safety • UK Department of Trade and Industry (now the Department for Business Innovation & Skills), *The General Product Safety Regulations 2005 – Guidance for businesses, consumers and enforcement authorities, August 2005* • European Commission Directorate General for Health and Consumers guidance on Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety • European Commission Directorate General for Health and Consumers, *Risk assessment guidelines for consumer products, November 2007* • European Commission Directorate General for Health and Consumers Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)
	Useful contacts: • Relevant Government departments take the lead on different sectors when it comes to safety requirements. For example: • food safety is covered by the Food Standards Agency; • medicines and healthcare is covered by the Medicines and Healthcare products Regulatory Agency; • vehicles are covered by the Vehicles and Operator Services Agency (VOSA).

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

Regulation	Summary
A.1.11 Consumer protection	*What:* Consumer Protection Act 1987
	Who: Manufacturers or importers of products, as well as "own branders" (i.e. someone who attaches their name to a product to give the impression that they are the manufacturer).
	How: Consumers injured by defective products might be able to sue for damages on a strict liability basis. This means that there is no need to prove negligence on the part of the manufacturer. If the product is unsafe and causes injury then the injured person (whether or not they bought the product themselves) can sue for compensation. The consumer need only prove that the defective product caused the injury. A product is defective where the safety of the product is not such as persons generally are entitled to expect. A claim must be made within three years of the date of injury or damage or the date on which the injury or damage was known to the claimant. In addition, there are a number of defences open to any claim.
	Sources of information: • Annex F, Consumer safety • European Union consumer policy website • UK Department of Trade and Industry (now the Department for Business Innovation & Skills), *Guide to the Consumer Protection Act 1987 – Product Liability and Safety Provisions*
	Useful contacts: • Trading Standards Institute

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

Regulation	Summary
A.1.12 Environmental permitting (England and Wales) – Discharge of listed substances	*What:* The Environmental Permitting (England and Wales) Regulations 2010, Schedule 22 (as amended)
	Who: Those who discharge certain substances into groundwater (i.e. water below the soil, but in contact with the soil). This includes the discharge of a pollutant that results in or might lead to a direct or indirect input to groundwater. "Pollutant" is widely defined as any substance liable to cause pollution. "Pollution" means the direct or indirect introduction, as a result of human activity, of substances or heat into the air, water or land which may: a) be harmful to human health or the quality of aquatic ecosystems or terrestrial ecosystems directly depending on aquatic ecosystems; b) result in damage to material property, or c) impair or interfere with amenities or other legitimate uses of the environment.
	How: An environmental permit will be required from the Environment Agency for anyone who discharges pollutants into groundwater. A permit might not be needed if the discharge of the pollutant: a) is the consequence of an accident or unforeseen natural event; b) is of a quantity so small as to pose no risk to groundwater; or c) cannot, subject to conditions, be prevented.
	Sources of information: • Annex G, Environment protection • There is as yet no specific guidance for groundwater discharges and environmental permits. However, more general guidance on environmental permits (with some commentary on groundwater discharges) is given by the Department for Environment, Food and Rural Affairs, *Environmental Permitting Guidance – Core guidance – For the Environmental Permitting (England and Wales) Regulations 2010, March 2013*
	Useful contacts: • Environment Agency

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

Regulation	Summary
A.1.13 Environmental permitting (England and Wales) – Discharge trade effluent and water quality	*What:* The Environmental Permitting (England and Wales) Regulations 2010, Schedule 21 (as amended)
	Who: Anyone who discharges poisonous, noxious or polluting matter; waste matter; trade effluent (i.e. liquid waste from business premises) or sewage effluent into certain "controlled waters". "Controlled waters" include inland freshwaters, coastal waters or relevant territorial waters, for example, rivers, streams or canals). The terms "poisonous", "noxious" and "polluting" are not defined in the regulation, although it is possible that nanomaterials could fall within the understanding of the term "polluting".
	How: An environmental permit might be required from the Environment Agency for discharges of poisonous, noxious or polluting matter; waste matter; trade effluent (i.e. liquid waste from business premises) or sewage effluent into certain "controlled waters". Certain activities are exempt from the need to obtain a permit. Any exempt water discharge activity must be registered with the regulator, and the regulator must be notified if the exempt water discharge activity ceases to be in operation. A discharge from a small sewage treatment plant (i.e. discharging five cubic metres per day or less of sewage effluent to inland freshwaters, coastal waters or relevant territorial waters) may be registered as an exempt water discharge activity, provided it meets certain conditions.
	Sources of information: • Annex G, Environment protection • Environment Agency guidance on how to apply for a discharge consent • The Department for Environment, Food and Rural Affairs, *Environmental Permitting Guidance – Water Discharge Activities – For the Environmental Permitting (England and Wales) Regulations 2010*
	Useful contacts: • Environment Agency

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

Regulation	Summary
A.1.14 Environmental permitting (England and Wales) – Regulated activities	*What:* The Environmental Permitting (England and Wales) Regulations 2010 (as amended)
	Who: Those who operate a "regulated facility" which is defined as any of the following: a) an installation; b) mobile plant; c) a waste operation; d) a mining waste operation; e) a radioactive substances activity; f) a water discharge activity; or g) a groundwater activity. Each of the above is defined more particularly in legislation (see Regulation 2), but examples of regulated facilities include installations (or buildings/plants) that manufacture chemicals and pharmaceuticals, those that manufacture and process metals as well as those that undertake waste management.
	How: Those who operate a "regulated facility" will need an environmental permit. Activities for which a permit might be required are split into three categories according to their environmental impact and type of permit they need: Part A(1), Part A(2) and Part B. Part A(1) activities are regulated by the Environment Agency; and Part A(2) and Part B activities are regulated by local councils.
	Sources of information: • Annex G, Environment protection • Department for Environment, Food and Rural Affairs environmental permitting website • Environment Agency environmental permitting website
	Useful contacts: • Environment Agency • Local councils (see GOV.UK directory of local council contact details)

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

Regulation	Summary
A.1.15 Pollution prevention and control permits (Northern Ireland and Scotland)	*What:* The Pollution Prevention and Control Regulations (Northern Ireland) 2003 (as amended). To be revoked by The Pollution Prevention and Control (Industrial Emissions) Regulations (Northern Ireland) 2013, with effect from 7 January 2014. The Pollution Prevention and Control (Scotland) Regulations 2012
	Who: Anyone whose business activities include certain "regulated processes". For example, those businesses that manufacture chemicals and pharmaceuticals as well as those that manufacture and process metals.
	How: A pollution prevention and control (PPC) permit might be needed for certain business activities in Northern Ireland and Scotland. These PPC permits are similar to, but different from, the environmental permitting regime in England and Wales. In Northern Ireland, applications for PPC permits are made either to the Industrial Pollution and Radiochemical Inspectorate (IPRI) or to the district council, depending on the nature of the business. In Scotland, the Scottish Environmental Protection Agency regulates all PPC permitted sites.
	Sources of information: • Annex G, Environment protection • Northern Ireland Environment Agency pollution prevention and control website • Scottish Environmental Protection Agency pollution prevention and control website
	Useful contacts: • Northern Ireland Environment Agency – Industrial Pollution and Radiochemical Inspectorate • Scottish Environmental Protection Agency

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

Regulation	Summary
A.1.16 Waste management licences (Northern Ireland and Scotland)	*What:* The Waste Management Licensing Regulations (Northern Ireland) 2003 (as amended) The Waste Management Licensing Regulations (Scotland) 2011 (as amended)
	Who: Those businesses in Scotland or Northern Ireland that operate a landfill, store other people's waste, treat waste, and/or carry out recycling or carry out final disposal of waste.
	How: A waste management licence will be required for those who operate landfills, store other people's waste or who carry out recycling or final disposal of waste. In Northern Ireland, the Northern Ireland Environment Agency is the appropriate regulator. In Scotland, it is the Scottish Environmental Protection Agency. It is unlikely that a waste management licence will be needed if the business only stores waste that it produces and an authorized waste carrier removes it from the site regularly (see **A.1.19**).
	Sources of information: • Annex G, Environment protection • Northern Ireland Environment Agency waste management licensing website • Scottish Environmental Protection Agency waste management licensing website
	Useful contacts: • Northern Ireland Environment Agency • Scottish Environmental Protection Agency

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

Regulation	Summary
A.1.17 Environmental damage prevention and remediation	*What:* The Environmental Damage (Prevention and Remediation) Regulations 2009 For a list of environmental damage and liability regulations in Northern Ireland and Scotland, see: NetRegs
	Who: Those companies whose business activities cause significant environmental damage. What constitutes significant environmental damage depends on the media that has been impacted (that is, whether there has been damage to species and habitats, damage to water or risks to human health from contamination of land). Establishing whether damage that has occurred (or will occur) is caught within the Regulations involves assessing whether the damage is above a particular threshold. Detailed advice on what damage qualifies can be found in Annex 1 of the Defra guide (see Sources of Information).
	How: There might be obligations on certain businesses to remedy significant damage to the environment. The Environment Agency, Natural England, local councils and the Secretary of State are responsible for administering and enforcing the regulations, depending on the type of damage involved. Liability might occur without any need for the regulator to show fault or negligence. Where damage is caused, the polluter must notify the regulator and then take steps to undertake remediation and prevent any further damage occurring. If business activities threaten environmental damage, steps must be taken to prevent the damage (or further damage) occurring and the relevant authority should be informed as soon as possible.
	Sources of information: • Annex G, Environment protection • The Department for Environment, Food and Rural Affairs environmental liability website • The Department for Environment, Food and Rural Affairs, *The Environmental Damage (Prevention and Remediation) Regulations 2009 – Guidance for England and Wales, November 2009*
	Useful contacts: • Environment Agency • Natural England • Local councils (see GOV.UK directory of local council contact details)

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

Regulation	Summary
A.1.18 Environmental protection – Waste duty of care	*What:* The Environmental Protection Act 1990, Section 34, which contains separate texts for England and Wales, and for Scotland The Environmental Protection Act (Duty of Care) Regulations 1991 For a list of environmental duty of care regulations in Northern Ireland and Scotland, see NetRegs
	Who: Anyone who produces, imports, keeps, stores, transports, treats or disposes of waste. This means almost every business in the UK.
	How: Anyone who produces or imports, keeps or stores, transports, treats or disposes of waste is under a duty of care to take all reasonable steps to ensure that all of the waste that they produce is disposed of in a safe and secure manner. Contractors who remove waste need to be registered with the Environment Agency in England and Wales and should be asked to provide copies of their Registered Waste Carrier certification. In Northern Ireland and Scotland, contractors need to notify the Northern Ireland Environment Agency or the Scottish Environmental Protection Agency at least three days before the waste is moved by completing a consignment note. A record must be made of all transfers of waste and copies kept for at least two years. Such records will give details of the types and quantities of waste collected and details of those who collect it and where it is taken for disposal. When completing the transfer documentation, waste must be described in writing using the European List of Waste, which is implemented in The List of Wastes (England) Regulations 2005 (as amended), The List of Wastes (Wales) Regulations 2005, The List of Wastes (Northern Ireland) Regulations 2005 (as amended) and for Scotland the Special Waste Regulations 1996 as amended by the Special Waste Amendment (Scotland) Regulations 2004.
	Sources of information: • Annex G, Environment protection • The Department for Environment, Food and Rural Affairs, *Environmental Protection Act 1990, Section 34, Waste Management, The Duty of Care, A Code of Practice* • Environmental Agency waste transfer notes website
	Useful contacts: • Environment Agency

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

Regulation	Summary
A.1.19 Hazardous waste	*What:* The Hazardous Waste (England and Wales) Regulations 2005 (as amended) The Hazardous Waste (Northern Ireland) Regulations 2005 (as amended) The Special Waste Regulations 1996 as amended by the Special Waste Amendment (Scotland) Regulations 2004
	Who: Those who produce or remove "hazardous waste". There are a wide variety of substances classified as "hazardous waste", including all those listed in the European List of Waste (see **A.1.18**) with an asterisk after the substance name. Some of the hazardous wastes in the list are classed as "absolute" hazardous waste, which means that no matter the circumstances the waste will always be hazardous. If a material is an absolute hazardous waste at the bulk scale, it will be an absolute hazardous waste at the nanoscale.
	How: It is an offence to produce hazardous waste at premises, or remove that waste from premises, unless those premises are either registered with the environment regulator (see *Useful contacts*) or are exempt. All types of premises that produce hazardous waste are exempt from registration if no more than 500 kg of hazardous waste is produced in a year. All hazardous wastes must be handled, stored and consigned in a manner consistent with maximum risk reduction in terms of accidental release and harm to persons or the environment.
	Sources of information: • Annex G, Environment protection • Environment Agency hazardous waste website • Northern Ireland Environment Agency hazardous waste website • Scottish Environment Protection Agency special waste website
	Useful contacts: • Environment Agency • Northern Ireland Environment Agency • Scottish Environment Protection Agency

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

Regulation	Summary
A.1.20 Packaging waste	*What:* The Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (as amended) Producer Responsibility Obligations (Packaging Waste) Regulations (Northern Ireland) 2007 (as amended) Packaging (Essential Requirements) Regulations 2003 (as amended)
	Who: Businesses which: a) handle more than 50 tonnes of packaging a year; and b) have a turnover in excess of £2 million per annum.
	How: There are obligations to: a) register with an environmental regulator, either directly or through a scheme specifically designed to help those with obligations to comply; b) pay for the recovery and recycling of certain amounts of packaging waste; and c) provide certain data on packaging use and recovery to the environmental regulator. Records of compliance must be kept for at least four years. In addition, there are also obligations under the Packaging (Essential Requirements) Regulations 2003 on every business that produces packaged goods or places packaging or packaged goods on the market. Here, the obligations are to minimize packaging weight and volume and to make sure packaging has a minimal impact on the environment after disposal. The Environment Agency is the relevant regulator for England and Wales, with the Northern Ireland Environment Agency responsible for Northern Ireland and the Scottish Environmental Protection Agency responsible for Scotland.
	Sources of information: • Annex G, Environment protection • European Union summary of packaging and packaging waste regulation • Environment Agency waste packaging website • Northern Ireland Environment Agency packaging waste website • Scottish Environment Protection Agency packaging waste website
	Useful contacts: • Environment Agency • Northern Ireland Environment Agency • Scottish Environment Protection Agency

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

Regulation	Summary
A.1.21 End-of-life vehicles (ELV)	*What:* End-of-Life Vehicles Regulations 2003 (as amended) The End-of-Life Vehicles (Storage and Treatment) (Scotland) Regulations 2003
	Who: Those who manufacture or import cars or vans below 3.5 tonnes.
	How: Those who manufacture or import cars or vans below 3.5 tonnes need to register with the ELV Registrations Unit and have in place a system for the take back of vehicles at the end of their life. At the end of its life, the vehicle should be depolluted and certain hazardous materials removed. In addition, there are also restrictions on the use of the following heavy metals in vehicles: cadmium; lead; mercury; and hexavalent chromium.
	Sources of information: • Annex G, Environment protection • European Union summary of end-of-life vehicles regulation • The Department for Business Innovation & Skills end-of-life vehicles website • The Department for Business Innovation & Skills *The End of Life Vehicles Regulations 2003, 2005 and 2010 – Government Guidance Notes, June 2010* • Environment Agency end-of-life vehicles website • Northern Ireland Environment Agency end-of-life vehicles website • Scottish Environment Protection Agency end-of-life vehicles website
	Useful contacts: • The Department for Business Innovation & Skills – End-of-Life Vehicle Registrations Unit • Environment Agency • Northern Ireland Environment Agency • Scottish Environment Protection Agency

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

Regulation	Summary
A.1.22 Waste electrical and electronic equipment (WEEE)	*What:* The Waste Electrical and Electronic Equipment Regulations 2006 (as amended) For a list of WEEE regulations and amendments in each of the devolved UK administrations, see Legislation.gov.uk.
	Who: Those who generate, handle or dispose of waste that falls under one of the ten categories of WEEE. The categories are: 1) large household appliances; 2) small household appliances; 3) IT and telecommunications equipment; 4) consumer equipment; 5) lighting equipment; 6) electrical and electronic tools; 7) toys, leisure and sports equipment; 8) medical devices; 9) monitoring and control equipment; and 10) automatic dispensers.
	How: Producers (that is, manufacturers, importers and "own branders") of electrical and electronic equipment are required to join a producer compliance scheme, which registers them with the appropriate environmental regulator. Fees are then paid to the compliance scheme operator who arranges to collect, treat and recycle WEEE on behalf of their members. There are certain exemptions from the obligations in relation to WEEE, including for large scale industrial tools and equipment designed to protect the UK's national security.
	Sources of information: • Annex G, Environment protection • European Union summary of waste electrical and electronic equipment • Environment Agency waste electrical and electronic equipment website • Northern Ireland Environment Agency waste electrical and electronic equipment website • Scottish Environment Protection Agency waste electrical and electronic equipment
	Useful contacts: • Environment Agency • Northern Ireland Environment Agency • Scottish Environment Protection Agency

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

Regulation	Summary
A.1.23 Batteries and accumulators	*What:* Waste Batteries and Accumulators Regulations 2009 Batteries and Accumulators (Placing on the Market) Regulations 2008 (as amended) For a list of waste battery and accumulator regulations and amendments in each of the devolved UK administrations, see Legislation.gov.uk.
	Who: Manufacturers, importers, sellers and distributors of batteries together with waste treatment sites and waste battery exporters.
	How: Businesses which manufacture or import batteries must label them with standard symbols to show that they must be recycled and not sent to landfill. In addition, there are limits on the amount of lead, cadmium and mercury that are permissible in batteries. Battery producers who produce more than one tonne of batteries each year are obliged to join a battery compliance scheme and pay fees to that scheme for the cost of recycling separately collected portable batteries. If the business produces one tonne or less of portable batteries per year then the obligation is instead to register with the relevant environmental regulator using the National Packaging Waste Database.
	Sources of information: • Annex G, Environment protection • European Union disposal of spent batteries and accumulators website • The Department for Business Innovation & Skills, *The Waste Batteries and Accumulators Regulations 2009: Government Guidance Notes* • Environment Agency waste battery and accumulator website • Northern Ireland Environment Agency waste battery and accumulator website • Scottish Environment Protection Agency waste battery and accumulator website
	Useful contacts: • Environment Agency • Northern Ireland Environment Agency • Scottish Environment Protection Agency

Annex B (informative) Regulation applicable to particular product types

A summary of regulation identified as being applicable to particular product types is given in Table B.1.

Table B.1 – Regulation applicable to particular product types

Regulation	Summary
B.1.1 Biocidal products regulations	*What:* Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products
	Who: Any person responsible for producing a biocidal product available on the EU market (e.g. manufacturers, importers and distributors).
	How: The regulation defines a "biocidal product" as: "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action"; or "any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action". A biocidal product cannot be placed on the EU market without authorization. Authorization can only be obtained if the active substance contained in that biocidal product has been approved under the regulation. The list of approved active substances is contained in Article 9 of the regulation. Companies wishing to place a biocidal product on the market containing an active substance that has not yet been approved under the regulation (i.e. it is not listed in regulation 9) must first submit an application to the European Chemical Agency. For details, see the HSE's website on Active Substance Approval. The regulation imposes certain conditions on approval (see Article 4). One condition is that the approval of an active substance shall not cover nanomaterials except where explicitly mentioned [see Article 4(4)]. This means that active substances listed as "approved" in regulation 9 shall not include nanomaterial variants of those substances, unless specifically stated in the approved list. For the purposes of the regulation, nanomaterial means a natural or manufactured active substance or non-active substance 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 to 100) nm [see Article 3(1)(z)].

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
	Companies wishing to place a biocidal product containing an approved active substance on the UK market must obtain authorization from the HSE (the UK's Competent Authority for biocides). Details of the application process can be found on the HSE's biocides website. Applications for authorization must be submitted via the European Chemical's Agency's R4BP system. Certain biocidal products qualify for the simplified authorization procedure, which reflects the principle that once an active substance has been authorized in one Member State, it can be freely marketed within the EU provided the Member State is notified before the active substance is placed on the market and no objections are raised by the other Member States (see Articles 19 and 25). Biocidal products containing nanomaterials do not qualify for the simplified authorization procedure [see Article 25(c)]. Companies wishing to place a biocidal product containing nanomaterials on the market are required to submit additional information as part of the authorization procedure. These additional requirements are set out in Article 19. One condition imposed is that authorization shall not be granted unless, where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately [see Article 19(1)(f)]. Once authorized, biocidal products shall conform to certain other requirements of market entry. Companies responsible for placing a biocidal product on the market must ensure the product label provides certain information (see Article 58). The label must include, among other things, the name of all nanomaterials contained in the biocidal product, followed by the word "nano" in brackets [see Article 58(3)(d)], and information on any specific related risks [see Article 69(2)(b)]. Certain biocidal products (specifically, non-agricultural pesticides) also fall within the remit of the Control of Pesticides Regulations (COPR) 1986. For details, see Annex H.
	Sources of information: • Annex H, Regulated products • Health and Safety Executive, guidance on placing biocidal products on the UK market • Health and Safety Executive frequently asked questions about biocidal products
	Useful contacts: • Health and Safety Executive – Chemicals Regulation Directorate
B.1.2 Cosmetic products regulations	*What:* Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products The Cosmetic Products Enforcement Regulations 2013
	Who: Any person responsible for placing cosmetics on the market. The responsible person might be a manufacturer, an importer or a distributor, depending on the circumstances (e.g. for a cosmetic product manufactured in the European Community, the manufacturer shall be the responsible person). For full details, see Article 4. A cosmetic product is defined in Article 2(1)(a) as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours".

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
	How: The EU Cosmetic Regulation No 1223/2009, came into force on 11 July 2013 replacing earlier EU legislation. The new Cosmetics Regulation demands a safety assessment of nanomaterials, the filing of information with the European Commission and labelling/ informational requirements. Passed before the Commission Recommendation 2011/696/EU the following separate definition of nanomaterial: "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from (1 to 100) nm" This is a more limited definition than that in the Recommendation being confined to man-made nanomaterials that are also insoluble or biopersistent and excluding natural and incidental nanomaterials. As previously explained, the definition in the Recommendation is likely to be varied in particular regulatory contexts, though in the Cosmetics Regulation it is unclear whether the more restricted definition includes aggregates or agglomerates of nanomaterials. Any person responsible for the placing cosmetics in the EU market must ensure, where these contain nanomaterials that the toxicological profile of all substances in the cosmetic product are assessed with particular attention being given to nanomaterials. Where a question of safety is raised, the Commission will request an opinion from an advisory body, which may lead to a restriction on use or a ban of certain substances in cosmetics. Where data is inconclusive, the onus is placed back on the persons placing the cosmetics on the market to provide the data within a stated time period. There is a notification requirement for cosmetics containing nanomaterials (with some exemption for colourants, UV filters and preservatives) such that six months prior to their marketing, the responsible person should report to the Commission with: • the identification of the nanomaterial; • its specifications, including particle size and physical and chemical properties; • the estimated, annual quantity of nanomaterials intended to be placed on the market in cosmetic products; • the toxicological profile of the nanomaterial; • safety data for the nanomaterial in the context of its cosmetic usage; and • reasonably foreseeable conditions of exposure. Notifications will be catalogued by the Commission and the Cosmetics Regulation demands periodic review, beginning in July 2018, by the Commission of the regulation of nanomaterials in cosmetics. Meanwhile, nanomaterial ingredients in cosmetics must be clearly labelled in the list of ingredients on the product with the word "nano" in brackets.
	Sources of information: • Annex H, Regulated products • European Union summary of cosmetic products legislation
	Useful contacts: • European Commission, Directorate for Health and Consumers • Department for Business Innovation & Skills (BIS). [BIS remains the competent authority in respect of cosmetics regulation under Regulation (EC) 1223/2009, though the day-to-day responsibility for enforcement falls to local authority trading standards departments]

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.3 Detergents regulations	*What:* Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (as amended) Implemented in the UK by The Detergents Regulations 2010 (as amended)
	Who: Manufacturers of detergents. Detergent is defined as any substance or preparation containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household or institutional or industrial purposes.
	How: Manufacturers of detergents do not have to request prior approval of their detergent, but they must ensure that they only place on the market detergents which meet the requirements of the regulations. These requirements relate to issues such as: • biodegradability and safety testing; • record keeping; • labelling; • composition; and • restricted and prohibited substances.
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Enterprise and Industry guidance on detergents • Health and Safety Executive guidance on detergents
	Useful contacts: • Health and Safety Executive – Chemicals Regulation Directorate

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.4 Electrical equipment (safety) regulations	*What:* Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits Implemented in the UK by The Electrical Equipment (Safety Regulations) 1994
	Who: Anyone wishing to place electrical equipment on the EU market. Certain electrical equipment is excluded from the scope of the Directive but is covered by other EU regulation, such as electrical equipment for radiology and medical purposes.
	How: Electrical equipment cannot be placed on the EU market unless it is safe. Products are presumed to conform to the safety requirements where the electrical equipment has been manufactured in accordance with certain harmonized, international or national technical standards. Alternatively, where technical standards have not been complied with, the manufacturer and/or supplier must ensure conformity to the safety requirements of the directive. Before placing on the market, manufacturers/suppliers must compile technical documentation on safety, issue a declaration of conformity to the safety requirements and affix a CE mark to the equipment. The CE marking is, in particular, an indication that the products conform to the essential requirements of the directive and that the products have been subject to a conformity assessment procedure provided for in the directive. To ensure compliance, manufacturers and suppliers might wish to have the electrical equipment assessed by a notified body.
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Enterprise and Industry guidance on the low voltage directive • European Commission Directorate General for Enterprise and Industry list of standards harmonized with the low voltage directive • UK Department of Trade and Industry (now the Department for Business Innovation & Skills) guidance notes on the UK Electrical Equipment (Safety) Regulations 1994, March 2007
	Useful contacts: • Enquiries about electrical equipment standards should be made to the British Standards Institution (BSI) via the BSI Knowledge Centre • European Commission Directorate General Enterprise and Industry list of notified bodies for the European low voltage directive

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.5 Fertilizer regulations (Europe)	*What:* Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (as amended) In the UK this directive is implemented by The EC (England and Wales) Fertilizers Regulations 2006, The EC (Scotland) Fertilizers Regulations 2006 and the EC (Northern Ireland) Fertilizers Regulations 2006
	Who: Manufacturers of European Commission designated fertilizers.
	How: Manufacturers cannot place a fertilizer on the EU market unless it is a designated EC fertilizer, that is: a) the fertilizer is listed in Annex I of the regulation; b) the manufacturer of the fertilizer is established in the EC; and c) the fertilizer conforms to all other requirements of the regulation, such as those relating to packaging and labelling, and record keeping. In order to obtain the EC fertilizer designation the manufacturer, or their representative, must apply via the competent authority in the Member State in which the manufacturer is established. In the UK, the competent authorities in relation to composition, labelling and records are local councils.
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Enterprise and Industry guidance on fertilizers • Department for Environment, Food and Rural Affairs fertilizers website
	Useful contacts: • Department for Environment, Food and Rural Affairs – Customer Contact Unit
B.1.6 Fertilizer regulations (UK)	*What:* The Fertilizer Regulations 1991
	Who: Manufacturers of non-EC designated fertilizers.
	How: Manufacturers must ensure they comply with requirements relating to: a) the name and description of fertilizers (regulations 4 and 5, and schedule 1); and b) the marking, labelling and packaging of fertilizers when sold for use (regulation 5 and schedule 2).
	Sources of information: • Annex H, Regulated products • Department for Environment, Food and Rural Affairs, Fertilizer Manual
	Useful contacts: • Trading Standards Institute

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.7 General food regulations	*What:* The General Food Regulations 2004
	Who: Anyone wishing to place a food or food ingredient on the EU market. The regulation also applies to anyone exporting food or food ingredients from the EU to other countries (unless the authorities from the importing country have requested otherwise, or it complies with the legal and regulatory requirements of the importing country). Certain provisions also apply to food business operators to whom food, food substances and foodproducing animals are supplied, and whose foods are supplied to other businesses.
	How: Persons responsible for placing on the market must ensure that the food or food ingredient: a) is not unsafe; b) are not nutritionally disadvantageous to the consumer; and c) is properly presented and labelled in a manner that does not mislead the consumer. Food business operators are obliged to keep records of the food, food substances and food-producing animals supplied to their business, and also other businesses to which their products have been supplied. This information shall be made available to competent authorities on demand. In the UK the competent authority is the Food Standards Agency (FSA).
	Sources of information: • Annex H, Regulated products • Food Standards Agency guidance on general food law
	Useful contacts: • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.8 Novel foods and novel food ingredients	*What:* Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients Implemented in the UK by The Novel Foods and Novel Food Ingredients Regulations 1997
	Who: Any person wishing to place a novel food or food ingredient on the EU market. Novel foods or food ingredients are those which were not generally available for human consumption in the EU prior to 15 May 1997 and: • contain, consist of, or were produced from genetically modified organisms (GMOs); • have a new or intentionally modified primary molecular structure; • consist of or are isolated from microorganisms, fungi or algae; • consist of or are isolated from plants, or constitute food ingredients isolated from animals (except for food and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use); or • have been subject to a production process not currently used, giving rise to significant changes in their composition or structure which affects their nutritional value, metabolism or level of undesirable substances.
	How: Novel foods or food ingredients cannot be placed on the EU market unless they have prior approval from the European Commission. Manufacturers and suppliers wishing to market a novel food or food ingredient must submit an application to the competent authority of the Member State in which the product will be placed for the first time. In the UK, the competent authority is the Food Standards Agency (FSA). A copy of the application must also be submitted to the European Commission. Applications must contain certain information, such as information on the composition, nutritional value, production process, toxicology, and safety of the novel food in question. Not all novel foods or food ingredients have to undergo this application and assessment process. Novel foods or food ingredients that are "substantially equivalent" to existing food or food components are subject to a simplified procedure.
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Health and Consumers guidance on novel foods and novel food ingredients • Food Standards Agency, Advisory Committee on Novel Foods and Processes (ACNFP) guidance on submitting a novel food application • European Commission, *Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports*
	Useful contacts: • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.9 Food labelling	*What:* The General Food Regulations 2004 Food Labelling Regulations 1996 Food Labelling Regulations (Northern Ireland) 1996 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers
	Who: Any person who manufactures, packages or sells foodstuffs within the EU.
	How: Manufacturers and suppliers must ensure that foodstuffs are adequately labelled. The labelling and presentation of foodstuffs must not mislead consumers. In addition, foods must be labelled with certain information such as its name, ingredients, durability, storage conditions, the name of manufacturer, packer or seller established within the European Community, its origin, and instructions for use. These requirements are now largely consolidated in European Regulation (EU) No 1169/2011 on the provision of food information to consumers, which will be brought into effect for most purposes by 2014 (and by 2016 for nutrition labelling). Note in particular, once in force, Article 19 (4) of this regulation will require that all ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients should be followed by the word "nano" in brackets. European Regulation (EU) No 1169/2011 begins to take effect in 2014 and a draft Food Information (England) Regulations 2013 is considering matters of enforcement. Until this takes effect, regulation does not require that labels include details of the particle size of ingredients. However, such details can be included voluntarily. There are other, more detailed labelling requirements for certain foods such as bread and flour, cocoa and chocolate, soluble coffee, evaporated and dried milk, fruit juice, honey, infant formula, jams, meat products: sausages, burgers and pies, natural mineral waters, spreadable fats and sugars.
	Sources of information: • Annex H, Regulated products • Food Standards Agency, *The Food Labelling Regulations 1996: Guidance Notes* (archived whilst information is transferred to the Department for Environment, Food and Rural Affairs) • Food Standards Agency, *Food Labelling – Clear Food Labelling Guidance, 2008* • European Commission Directorate General for Health and Consumers guidance on food labelling
	Useful contacts: • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.10 Genetically modified (GM) food	*What:* Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed Implemented in the UK by The Genetically Modified Food (England) Regulations 2004 The Genetically Modified Animal Feed (England) Regulations 2004 The Genetically Modified Food Regulations (Northern Ireland) 2004 The Genetically Modified Animal Feed (Northern Ireland) Regulations 2004 The Genetically Modified Food (Scotland) Regulations 2004 The Genetically Modified Animal Feed (Scotland) Regulations 2004 The Genetically Modified Food (Wales) Regulations 2004 The Genetically Modified Animal Feed (Wales) Regulations 2004 And Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC Implemented in the UK by The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004 The Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004 The Genetically Modified Organisms (Traceability and Labelling) (Wales) Regulations 2005 The Genetically Modified Organisms (Traceability and Labelling) (Northern Ireland) Regulations 2005
	Who: Any person wishing to place a GM food or feed product on the EU market. GM food or feed means food or feed containing, consisting of or produced from genetically modified organisms (GMOs).
	How: GM food and feed cannot be placed on the EU market unless they are authorized. Applications for authorization can be submitted to the competent authority of the Member State in which the foods are first marketed. In the UK the competent authority is the Food Standards Agency (FSA). GM foods placed on the EU market must not have adverse effects on human health, animal health or the environment; mislead the consumer; or differ from the non-GM food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer. The regulation requires the labelling of all GM food and feed which contains or consists of GMOs (such as GM soya); are produced from GMOs (such as glucose syrup from maize starch); or contain ingredients produced from GMOs (such as GM tomato paste containing lecithin from GM soya). Labelling is necessary even if there is no detectable GM material in the final product. The labelling requirement does not apply, however, where the presence of GMOs is accidental or technically unavoidable and constitutes no more than 0.9% of the food or feed ingredients. All persons who place a GM food product on the market or receive a GM food product placed on the market within the EU must be able to identify their supplier and the companies to which the products have been supplied. Traceability provisions require operators to transmit certain information to operators receiving GMO foods.

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Health and Consumers guidance on GM food and feed • European Union summary of GMO regulation • Food Standards Agency guidance on GM foods • Food Standards Agency and Department for Environment, Food and Rural Affairs *Guidance Notes on Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003* • Food Standards Agency Scotland and Scottish Executive *Guidance Notes on Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003* • Food Standards Agency Wales and the National Assembly for Wales *Guidance Notes on Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003*
	Useful contacts: • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales
B.1.11 Contained use of genetically modified organisms (GMOs)	*What:* Environmental Protection Act 1990 and the following regulation made under its authority: The Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended) The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations (Northern Ireland) 1996
	Who: Employers, including self-employed persons and employers in educational establishments.
	How: Employers are required to conduct a risk assessment of activities involving GMOs and genetically modified microorganisms (GMMs). All activities must be assessed for risk to humans and those involving GMMs assessed for risk to the environment. Employers must notify the Health and Safety Executive (HSE) of all premises before they are used for genetically modified (GM) activities for the first time, and of all individual activities involving GM within certain risk categories. Activities in medium and high risk categories require prior approval from the HSE. Employers are also responsible for maintaining a public register of GM premises and certain GM activities.
	Sources of information: • Annex H, Regulated products • Health and Safety Executive overview of the contained use of GMOs
	Useful contacts: • Health and Safety Executive – Hazardous Installations Directorate – Specialised Industries Division – Biological Agents Unit

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.12 Deliberate release of genetically modified organisms (GMOs)	*What:* The Genetically Modified Organisms (Deliberate Release) Regulations 2002 (as amended) The Genetically Modified Organisms (Deliberate Release) (Northern Ireland) Regulations 2003 (as amended) The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (as amended) The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (as amended)
	Who: Any person responsible for the deliberate release of GMOs and/or placing GMOs on the EU market.
	How: Before a GMO is deliberately released or placed on the market, the persons responsible are required to take several steps, such as: a) conduct a risk assessment; b) submit an application for authorization to the relevant competent authority, which in the UK is the Health and Safety Executive (HSE) together with a technical dossier and certain safety information; and c) notify the competent authority. Where GMOs are placed on the market, persons responsible must ensure they comply with GM labelling and traceability requirements (see **B.1.10** and **B.1.11**).
	Sources of information: • Annex H, Regulated products • Department for Environment Food and Rural Affairs overview on genetic modification
	Useful contacts: • Department for Environment Food and Rural Affairs – Customer Contact Unit

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.13 Food additives	*What:* Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives Implemented in the UK by The Food Additives (England) Regulations 2009 The Food Additives (Northern Ireland) Regulations 2009 The Food Additives (Scotland) Regulations 2009 The Food Additives (Wales) Regulations 2009 And Regulation (EC) No 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavourings Implemented in the UK by The Food Enzymes Regulations 2009 The Food Enzymes Regulations (Northern Ireland) 2009 The Food Enzymes Regulations (Scotland) 2009 The Food Enzymes Regulations (Wales) 2009
	Who: Any person wishing to place food additives on the EU market. Food additives include, for example, sweeteners, colours, preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents and bulking agents.
	How: Persons responsible should check if the food additive they wish to market is contained in Annexes II or III to European Regulation 1333/2008. Only those listed may be placed on the market, subject to specified conditions. Where food additives are not included in either Annex, manufacturers may apply to the European Commission to have the list of authorized additives updated. If a food additive is already included in Annexes II or III, but the production methods or raw materials are altered considerably (through, for example, the use of nanotechnology), the additive shall be considered a different additive. Before being placed on the market, the new additive shall be submitted to the European Food Safety Authority (EFSA) for an assessment of health risks. Food additives must also be adequately labelled.
	Sources of information: • Annex H, Regulated products • European Union summary of Regulation (EC) No 1333/2008 • European Union summary of Regulation (EC) No 1331/2008 • European Commission Directorate General for Health and Consumers guidance on food additives • Food Standards Agency guidance in food additives
	Useful contacts: • European Food Safety Authority • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales Contact your national regulator in the first instance.

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.14 Food additives purity criteria	*What:* Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council Implemented in the UK by The Purity Criteria for Colours, Sweeteners and Miscellaneous Food Additives (England) Regulations 2009 The Purity Criteria for Colours, Sweeteners and Miscellaneous Food Additives Regulations (Northern Ireland) 2009 The Purity Criteria for Colours, Sweeteners and Miscellaneous Food Additives (Scotland) Regulation 2009 The Purity Criteria for Colours, Sweeteners and Miscellaneous Food Additives (Wales) Regulations 2009 (as amended) And Regulation (EC) No 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavourings
	Who: Any person wishing to place food additives on the EU market.
	How: Persons responsible must ensure that, before being placed on the market, food additives are authorized and fulfil purity criteria set out in Annexes II and III of Regulation (EC) No 1333/2008 as reproduced in the Annex to Commission Regulation (EU) No 231/2012.
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Health and Consumers guidance on food additives • Food Standards Agency guidance in food additives
	Useful contacts: • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.15 Food supplements	*What:* Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements Implemented in the UK by The Food Supplements (England) Regulations 2003 (as amended) The Food Supplements (Scotland) Regulations 2003 (as amended) The Food Supplements (Northern Ireland) Regulations 2003 (as amended) The Food Supplements (Wales) Regulations 2003 (as amended)
	Who: Any person wishing to place food supplements on the EU market.
	How: Manufacturers are required to ensure that a food supplement they wish to market conforms to the composition and labelling requirements of the regulations. Only those vitamins and minerals listed in Schedules 1 and 2 of the regulations may be used in food supplements. Where a vitamin and mineral is not included in Schedules 1 or 2, manufacturers may apply to the European Commission Directorate General for Health and Consumers to have the list of authorized supplements updated, following evaluation by the European Food Safety Authority (EFSA).
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Health and Consumers administrative guidance on submission for safety evaluation of substances added for specific nutritional purposes in the manufacture of food • Department of Health guidance on food supplements • Department of Health, *Food supplements – Guidance notes on legislation implementing Directive 2002/46/EC on food supplement, September 2011*
	Useful contacts: • European Commission, Directorate General for Health and Consumers • European Food Safety Authority • Department of Health • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales • Welsh Government – Department for Public Health

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.16 Food flavourings	*What:* Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods Implemented in the UK by The Flavourings in Food (England) Regulations 2010 The Flavourings in Food Regulations (Northern Ireland) 2010 The Flavourings in Food (Scotland) Regulations 2010 The Flavourings in Food (Wales) Regulations 2010 And Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings Food Labelling Regulations 1996 Food Labelling Regulations (Northern Ireland) 1996
	Who: Any person wishing to place food flavourings on the EU market.
	How: Manufacturers should ensure that the food flavourings they wish to place on the market are authorized at EC level, and comply with certain restrictions and labelling requirements. Where a food flavouring is not already authorized, manufacturers may apply to the European Commission to have the list of permitted flavourings updated.
	Sources of information: • Annex H, Regulated products • European Commission Directorate General for Health and Consumers guidance on food flavouring
	Useful contacts: • European Commission, Directorate General for Health and Consumers • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.17 Food enzymes	*What:* Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes Implemented in the UK by The Food Enzymes Regulations 2009 The Food Enzymes (Northern Ireland) 2009 The Food Enzymes (Scotland) Regulations 2009 (as amended) The Food Enzymes (Wales) Regulations 2009 And Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings Food Labelling Regulations 1996 Food Labelling Regulations (Northern Ireland) 1996
	Who: Any person wishing to place food enzymes on the EU market.
	How: Food enzymes may not be placed on the market unless they are authorized at EC level. The regulations list all those enzymes that have been approved. Where an enzyme is not already authorized, manufacturers may apply to the European Commission to have the list of permitted flavourings updated. Manufacturers must also ensure that food enzymes are properly labelled.
	Sources of information: • Annex H, Regulated products • European Union summary of Regulation (EC) No 1332/2008 • European Commission, Directorate General for Health and Consumers guidance on food additives
	Useful contacts: • European Commission, Directorate General for Health and Consumers • Food Standards Agency – General • Food Standards Agency Northern Ireland • Food Standards Agency Scotland • Food Standards Agency Wales

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.18 Medicinal product marketing authorization	*What:* Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (as amended by Regulation (EU) No 520/2012) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (as amended by Regulation (EU) No 712/2012) Directives Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products Implemented in the UK by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (as amended) The Human Medicines Regulations 2012 The Medicines (Products for Human Use) (Fees) Regulations 2013
	Who: Anyone wishing to place a medical/medicinal products on the EU market.
	How: Persons responsible must submit an application for authorization to the competent authority of the Member State in which the medical product is first marketed. In the UK the competent authority is the Medicines and Healthcare products Regulatory Agency (MHRA). Applications must be accompanied by a common technical dossier. The European Medicines Agency is responsible for the scientific evaluation of applications for centralized marketing authorizations. All human medicines derived from biotechnology and advanced therapy medicines and products containing new active substances must be centrally authorized. Note that the Human Medicines Regulations 2012 (Statutory Instrument No 2012/1916) came into force on 14 August 2012 consolidating the law on medicinal products for humans, setting out a comprehensive regime for the authorization of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance. For the most part the regulations implement Directive No 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use (as amended).

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
	Sources of information: • European Commission Directorate General for Health and Consumers regulatory guidance on medicinal products for human use • Medicines and Healthcare products Regulatory Agency guidance on medicinal product marketing authorizations • Medicines and Healthcare products Regulatory Agency, *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 "Orange Guide"*
	Useful contacts: • European Medicines Agency • Medicines and Healthcare products Regulatory Agency – Regulatory Information Service for medicines
B.1.19 Medicinal product parallel import licence	*What:* Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency Implemented in the UK by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (as amended) The Human Medicines Regulations 2012 The Medicines (Products for Human Use) (Fees) Regulations 2013
	Who: Anyone wishing to place a medical product on the UK market that has already been authorized in other European Member States.
	How: Manufacturers must obtain a parallel import licence from the Medicines and Healthcare products Regulatory Agency (MHRA) before a medical product can be placed on the UK market.
	Sources of information: • Annex H, Regulated products • Medicines and Healthcare products Regulatory Agency guidance on parallel import licences
	Useful contacts: • Medicines and Healthcare products Regulatory Agency – Parallel Import Section

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.20 Medicinal product manufacturer's and wholesale dealer's licence	*What:* The Human Medicines Regulations 2012
	Who: Manufacturers, importers and wholesale dealers of medical products.
	How: Manufacturers, importers and wholesale dealers must apply to the (Medicines and Healthcare products Regulatory Agency) MHRA for a licence before they can manufacture, import and wholesale deal medical products.
	Sources of information: • Annex H, Regulated products • Medicines and Healthcare products Regulatory Agency guidance on manufacturer's and wholesale license
	Useful contacts: • Medicines and Healthcare products Regulatory Agency – Process Licensing
B.1.21 Control of pesticides regulations (COPR)	*What:* The Control of Pesticides Regulations 1986 (as amended) The Control of Pesticides Regulations (Northern Ireland) 1987 (not available online, as amended)
	Who: Any person who advertises, sells, supplies, stores or uses pesticides.
	How: Before a pesticide can be advertised, sold, supplied, stored or used in the UK it has to be approved. Persons responsible must apply to the relevant regulatory authority and provide necessary data on safety, efficacy and, where appropriate, humaneness. Applications for agricultural pesticides must be submitted to the Health and Safety Executive (HSE).
	Sources of information: • Annex H, Regulated products • Health and Safety Executive guidance on pesticides
	Useful contacts: • Health and Safety Executive – Chemicals Regulation Directorate

Table B.1 – Regulation applicable to particular product types *(continued)*

Regulation	Summary
B.1.22 Plant protection products (PPP) regulations	*What:* Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Implemented in the UK by The Plant Protection Products Regulations 2011 The Plant Protection Products Regulations (Northern Ireland) 2011 (as amended) The Plant Protection Products (Sustainable Use) Regulations 2012 And Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
	Who: The regulation covers manufacturers wishing to market plant protection products containing certain active ingredients.
	How: Regulation No 1107/2009 lays down harmonized rules for the approval of active substances and the placing on the market of plant protection products and its main purpose is to ensure a high level of protection of both human and animal health and the environment. Manufacturers must ensure that a plant protection product is authorized by the European Commission and registered with the relevant competent authority before it is placed on the market. In the UK the competent authority is the Health and Safety Executive (HSE). The European PPP Regulations No 1107/2009 lays down requirements and conditions for approval of plant protection products. Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides and is transposed in the UK by the Plant Protection Products (Sustainable Use) Regulations 2012. The Directive demands that Member States adopt National Action Plans to reduce risk to human health and the environment posed by pesticide use. National Action Plans should have been submitted to the European Commission by 14 December 2012.
	Sources of information: • Annex H, Regulated products • European Commission, Directorate General for Health and Consumers guidance on plant protection products • Health and Safety Executive guidance on pesticides
	Useful contacts: • Health and Safety Executive – Chemicals Regulation Directorate

Annex C (informative) Registration, evaluation, authorization and restriction of chemicals

C.1 General

Regulation (EC) No 1907/2006 on the registration, evaluation, authorization and restriction of chemicals is commonly known as "REACH". REACH constitutes an umbrella regulatory regime for chemicals within the EU, placing an obligation for gathering testing data on the intrinsic properties of certain substances upon the private sector in the form of manufacturers, importers and, in limited circumstances, downstream users. It is overseen by the European Chemicals Agency (ECHA). Enforcement is a matter for national agencies. Chemicals must be registered directly with the ECHA.

In addition to REACH, there are other regulations which apply to research and development uses of specific "families" of chemicals, such as biocides and pesticides, which are administered by national agencies (in the UK, typically the Health and Safety Executive, certain of its directorates, and the Environment Agency). These regulations are not supplanted by REACH. Any requirements they impose upon research and development uses apply in addition to those which apply under REACH.

Finally, other bodies of regulation apply to different stages of a chemical's life cycle, from research and development through operational use to final disposal. Relevant occupational health regulation (see Annex E) will apply to laboratories, for example, and environmental regulation to the disposal of wastes (see Annex G).

C.2 Scope

REACH applies to "substances on their own, in preparations or in articles" where a substance is defined as "a chemical element and its compounds in the natural state or obtained by any manufacturing process". The definition of substance in REACH does not depend on particle size and thus, in principle, substances at the nanoscale are captured within REACH.

Certain substances are excluded from the ambit of REACH; others exempted. Certain of these exemptions or exclusions apply in full; others only exempt or exclude the class of substance from certain of the provisions of REACH. Those substances which are excluded or exempted and the reasons for such as set out in REACH are set out in Table C.1.

In addition to the substances set out in Table C.1, which are either excluded or exempted from REACH, two other classes of substances are "to be regarded as registered" (and thus are effectively exempt from a large part of the active obligations on manufacturers and importers under the regulation). The first class is certain substances manufactured or imported for use in "plant protection products" (namely, insecticides, herbicides, fungicides and other products); the second class are those substances manufactured or imported for use in "biocidal products" (broadly, disinfectants, pesticides, preservatives and other products).

C.3 Registration obligations

The registration obligation under Article 6 of REACH is volume-based with a one tonne de minimis threshold. A manufacturer or importer of any nanomaterial in quantities greater than one tonne per year will be captured under the REACH registration provisions. The obligation to register operates in respect of each legal entity within the European Community manufacturing or importing a substance or article captured by REACH.

The data which REACH requires to be submitted to the ECHA on manufactured or imported substances, and by when, depends on:

- the volume of substance; and

Those obliged to register are required to submit a registration dossier to ECHA, containing:

- a technical dossier; and
- for all substances manufactured or imported in quantities greater than ten tonnes per year per registrant, a chemical safety report (CSR).

Articles 10 and 12 and Annexes VI to XI of REACH detail the content of the technical dossier. Article 14 and Annex I of REACH detail the content of the CSR.

REACH operates on the principle of "one substance, one registration". On a practical level, REACH mandates the sharing of certain data between those manufacturers and importers intending to register the "same" substance. This data sharing is facilitated by a substance information exchange forum (SIEF),

Table C.1 – Substances excluded or exempted from REACH Regulation (EC) No 1907/2006

Substance	Exclusion/partial exemption	Justification and commentary
Wastes	Excluded	Exclusion "to ensure workability and to maintain the incentives for waste recycling and recovery" [see Recital (11) and Article 2(2)]
Substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to reexportation or in transit	Excluded	Such substances are not "used" as this term is understood within REACH [see Recital (10) and Article 2(1)(b)]
Dangerous substances and dangerous preparations carried by rail, road, inland waterways, sea or air	Excluded	Specific legislation already applies to such carriage [see Recital (10) and Article 2(1)(d)]
Substances manufactured in the European Community or imported for the purposes of product and process orientated research and development	Exemption from registration: Articles 5, 6, 7, 17, 18 and 21 do not apply for a period of five years	This exemption is granted to "encourage innovation" [see Recital (28) and Article 9(1)] Where seeking to take the benefit of this exemption, the relevant manufacturer or importer or producer needs to notify European Chemicals Agency (ECHA) of certain information and pay the relevant fee [see Article 9(2)]
Substances used in medicinal products for human or veterinary use [see Article 2(5)(a), providing that such products are within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC] or substances used in food or feeding stuffs in accordance with Regulation (EC) No 178/2002 [see Article 2(5)(b)]	Exclusion from registration, evaluation and authorization: Provisions of Titles II, V, VI and VII do not apply	Such exclusion is necessary to "avoid confusion" between the mission of ECHA and the missions of the European Medicines Agency and the European Foodstuffs Agency [see Recital (111)]
Substances which are necessary in the interests of defence	Case-by-case specific exemption	Member States may nominate certain substances for exemptions [see Article 2(3)]
Non-isolated intermediates [see Article 2(1)(c)]	Excluded	An intermediate means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance [Article 3(15)] A non-isolated intermediate means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place [Article 3(15)(b)]

Table C.1 – Substances excluded or exempted from REACH Regulation (EC) No 1907/2006 *(continued)*

Substance	Exclusion/partial exemption	Justification and commentary
Polymers	Excluded from registration and evaluation: Titles II and VI	Exclusion lasts "until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria" [see Recital (41)] Essentially, including polymers within REACH is thought to be too complicated for the present time. This topic was the subject of the first case on REACH before the UK and EU courts [see R (SPCM SA and Others) v Secretary of State for Environment, Food and Rural Affairs [2007] EWHC 2610 (Admin); and Case C–558/07, S.P.C.M. and others]
Radioactive substances within the scope of Council Directive 96/29/EURATOM of 13 May 1996 [see Article 2(1)(a)]	Excluded	There is no given reason for this exclusion in the text of REACH
Substances included in Annex IV	Exempted from Titles II, V and VI (i.e. from registration and evaluation)	It is though that sufficient information is known about these substances that they are to be considered minimum risk because of their intrinsic properties [see Article 2(7)(a)] The list in Annex IV includes substances such as argon and sunflower oil
Substances covered by Annex V	Exempted from Titles II, V and VI (i.e. from registration and evaluation)	Registration is deemed "inappropriate or unnecessary" for these substances and their exemption is not thought to prejudice the objectives of REACH [Article 2(7)(b)] Included in Annex V are substances which occur in nature (including natural gas, crude oil and minerals)
Substances on their own or in preparations, registered in accordance with Title II, exported from the European Community by an actor in the supply chain and reimported into the Community by the same or another actor in the same supply chain	Exempted from Titles II, V and VI (i.e. from registration and evaluation)	There is no stated reason for this exemption in REACH [see Article 2(7)(c)] Note, however, that this "substances in the same supply chain" exemption operates only in respect of registration (and not additionally pre-registration)
Substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the European Community [see Article 2(7)(d)]	Exempted from Titles II, V and VI (i.e. from registration and evaluation)	This "recovery" exemption is linked to the wastes exemption detailed above Note, however, that this is a complex area and one in which the European Commission has published draft guidance, which is available from: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/waste_paper_ca_090403_en.pdf

membership of which is compulsory for all potential registrants of the same substance (e.g. manufacturers, importers and only representatives) and optional for downstream users of the substance and other third parties who have submitted information to ECHA on that substance.

ECHA has produced detailed guidance on registration and data sharing under REACH, which is available from: http://echa.europa.eu/web/guest/guidance-documents/guidance-mainly-for-industry-use.

C.4 Substance bans

Each separate use of a "substance of very high concern" (SVHC) which is listed in Annex XIV of REACH will be subject to authorization by the European Commission. Without an authorization (which will be, in any event, time limited), the SVHC cannot be placed on the EU market. A number of substances are automatically considered as SVHCs (and thus could potentially require authorization). These fall into four broad categories: carcinogens, mutagens and reproductive toxins; those substances which are persistent, bio accumulative or toxic; substances which are very persistent or very bio accumulative; and finally, other substances which will be identified on a case-by-case basis. A more specific definition of SVHC is given in Table C.2.

Table C.2 – Definition of substances of very high concern (SVHC)

These are defined as meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1a or 1b in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures:

- substances which are persistent, bio-accumulative and toxic (PBT) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- substances which are very persistent and very bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- substances giving rise to an equivalent level of concern to substances meeting the above criteria. Such substances will be identified on a case-by-case basis.

Substances identified as SHVC are entered on the REACH Candidate List of substances, from which those substances listed in Annex XIV of REACH (substances subject to special authorization) are selected.

C.5 Research and development

Information provision requirements under REACH are significantly scaled down for purposes of research and development, which is defined in article 3(23) of REACH as "any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year". Currently, any substance manufactured or imported in a quantity of less than one tonne per year does not need to be registered. Further, substances used only for research and development do not fall under the REACH on the authorization and/or restriction of substances as stated in Articles 56(3) and 67(1) respectively.

It should be noted that REACH does not prevent companies from registering on a voluntary basis their substances if they are below the one tonne threshold. Some manufacturers might wish to undertake early registration (before scale-up of production above the tonnage limits) to demonstrate the safety of the substance. However, the associated costs could be very high, especially if testing of the substance for purposes of registration raised concerns about the impact the substance could have on human health and the environment.

Reporting requirements differ when manufactured or imported substances are to be used in what REACH defines as product or process orientated research and development (PPORD).Article 3(22) of REACH defines this as "any scientific development related to product development or the further development of a substance … in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance". Examples of PPORD might be:

- experimental scaling-up of an existing production process;
- development and testing of a new process for the manufacture of a substance, (e.g. testing a new catalyst), involving such changes as innovative equipment or significant alterations in the mass and heat transfer conditions;
- testing of a new intermediate for the synthesis of a substance; and
- development and testing of a new application for a substance.

There are further variations in requirements depending on whether whoever engaging in PPORD is:

- a manufacturer or importer; or
- a downstream user of manufactured or imported articles.

C.6 Manufacturing or importing

A manufacturer or importer can be exempted from the obligation to register the quantities of the substance manufactured or imported for the purpose of PPORD, by making a PPORD notification to the ECHA. Once this is done, a manufacturer or importer need not register a substance used in PPORD for up to 5 years. This exemption may, on request, be extended by the ECHA for a further 5 years (and up to 10 years if the PPORD is for substances used in either human or veterinary medicines or for substances that are not placed on the market). So long as substances are only used for PPORD, there is no upper limit at present on how much may be manufactured or imported. A notification can be made either for the notifier's own PPORD, or for activities undertaken together with listed customers.

Further information on what to consider when making a PPORD notification, and how to go about it, is available from the ECHA's REACH guidance website at http://guidance.echa.europa.eu/guidance_en.htm.

In addition to these requirements concerning PPORD notification, it is necessary to check Annex XIV of REACH which lists substances subject to authorization for information on whether use of a particular substance for PPORD needs to be authorized. If an authorization requirement does not apply to PPORD, this may only apply up to a particular quantity of the substance. It is worth noting, however, that substances which are subject to authorization and listed in Annex XIV may still be used for the purposes of scientific research and development. The list of substances which have been put forward under REACH to be included in the authorization list is available from: http://echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp.

Annex XVII of REACH lists substances whose use is subject to certain legal restrictions, and is also subject to updates. Guidance on restrictions is given at http://echa.europa.eu/reach/restriction_en.asp.

Again, restrictions may or may not apply to uses of substances for PPORD, and exemption from restriction may not apply beyond a maximum quantity.

In addition, information on substances not listed under either Annex XIV or Annex XVII, but which have properties that might cause them to be classified as SHVC should be recorded as a matter of good business practice, in case these substances are listed in the future under either annex.

If the PPORD is being conducted in concert with listed customers, then all customers must be supplied with a safety data sheet (SDS) under certain conditions. If the substances being used would be classified under REACH as PBT or vPvB (see Table C.1), then an SDS is required. One is also required if the substance already appears on the candidate list of substances which are already considered to be SHVC. Article 31(1) of REACH also requires suppliers of substances or mixtures to provide recipients with a SDS if the substance is classified as hazardous in accordance with Regulation (EC) No 1272/2008 or if a mixture meets the criteria for dangerous in accordance with Directive 1999/45/EC (see **A.1.2**).

Even if an SDS is not required, a supplier must nonetheless provide their customers with:

a) the registration number of the substance, if available;
b) any eventual authorization granted or denied in his supply chain;
c) any restrictions imposed; and
d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.

C.7 Downstream users

For a downstream user, using a substance for PPORD might impose obligations under REACH. This depends, in the first place, on whether the manufacturer/importer of the substance has already made a PPORD notification or not, and listed the user as one of their collaborating customers.

If a downstream user who is listed as a customer under a PPORD stops using the substance for PPORD, the user is required to inform the supplier, as the tonnage covered by the PPORD notification will change. This might alter the obligations which apply to the supplier.

If a downstream user intends to use a substance for PPORD without being a listed customer in a supplier's PPORD notification, then the standard obligations on downstream users under REACH apply with one exception. The user is not required to prepare a chemical safety report for PPORD uses. However, a downstream user might have an obligation to notify ECHA if they are using a registered substance for PPORD even if there is no duty on them to prepare a chemical safety report for this use. Further information on the standard obligations on downstream users is available from the ECHA REACH guidance website http://guidance.echa.europa.eu/guidance_en.htm.

Annex D (informative) Hazardous materials

D.1 Hazard information for chemicals

D.1.1 General

The purpose of the Chemicals (Hazard Information & Packaging for Supply) Regulations 2002 (CHIP) is to ensure that manufacturers and suppliers of chemicals provide all users of their products with sufficient appropriate information about the hazards associated with their products, and about what actions should be taken in the event of an emergency. These regulations apply to all substances manufactured for research and development purposes.

Internationally agreed criteria should be used to classify the hazards associated with the material. For example, the container used for storing hazardous chemicals must have an appropriate pictogram with an orange background and a symbol letter on the outside to identify the nature of the hazards associated with the chemicals within it. Containers must also include specific information on the hazards, and on appropriate precautions users should take. CHIP also requires manufacturers and suppliers of hazardous chemicals to provide a materials safety data sheet (MSDS) on the chemicals.

The MSDS should include information on:

a) the hazards which the chemicals might pose to human health and/or to the environment, including toxicological information and a summary of regulatory requirements regarding use;
b) actions to take if the chemicals are spilled;
c) appropriate fire-fighting methods; and
d) first aid requirements.

Suppliers of hazardous chemicals are required to classify, label and package those chemicals before placing them on the market. For the purposes of the law, suppliers include those who manufacture, import, re-import, mix, distribute or sell hazardous chemicals.

A "chemical" can be either a single substance (e.g. mercury) or a mixture of substances (e.g. ink or paint). The law in this area does not distinguish between chemicals at bulk and in the nanoscale. As a result, the requirements apply to chemicals in both forms.

The law in this area is in the process of being changed. A new regulation on the classification, labelling and packaging of substances and mixtures will gradually replace the existing law in this area. For the moment, however, the existing law still applies.

D.1.2 Existing requirements

The legal requirements are set out in the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (also known as "CHIP") (see **A.1.2**).

Suppliers of chemicals must establish whether those chemicals are "hazardous" according to criteria set out in CHIP. Many chemicals have already been classified and appear in the new Classification, Labelling and Packaging Regulation (Annex VI, Part 3, Table 3.2). Hydrogen, for example, is classified as "extremely flammable". Where a substance is has not already been classified, suppliers are required to classify the substance themselves taking into account all relevant and accessible data. The Approved Classification and Labelling Guide provides further information on the process of self-classification. Suppliers must ascertain which of the properties listed in CHIP apply, place the substance in one or more of the specified categories of danger (e.g. "explosive", "oxidizing", "extremely flammable"), and select appropriate risk phrases (e.g. "explosive when dry") to describe the hazard.

Where a chemical is classified as hazardous, suppliers must ensure that its packaging is labelled with certain information, including:

- the name and contact details of the person responsible for supplying the substance or mixture in the European Economic Community;
- the name of the substance or mixture;
- any indications of danger together with corresponding symbols; and
- risk phrases and safety phrases, set out in full.

Labels must be clear, indelible and securely fixed.

Packaging containing hazardous substances or mixtures must, among other things:

- be designed and constructed so that its contents cannot escape;
- not be susceptible to damage by the contents; and
- be strong enough to withstand normal handling.

D.1.3 New requirements

The Classification, Labelling and Packaging of Substances and Mixtures Regulation (EC) No 1272/2008 (commonly referred to as the "CLP Regulation") came into force on 20 January 2009. In order to give industry enough time to adapt to the new system, the regulation is being introduced over a period of seven and a half years. It is vital that suppliers and users of hazardous substances understand how and when the CLP Regulation will affect them:

- substances must be classified, labelled and packaged according to the CLP Regulation from 1 December 2010;
- substances already on the market on 1 December 2010 can continue to be supplied until 1 December 2012;
- mixtures must be classified, labelled and packaged according to the CLP Regulation from 1 June 2015; and
- mixtures already on the market on 1 June 2015 can continue to be supplied until 1 June 2017.

Manufacturers, importers and downstream users of chemicals must first determine whether, according to the criteria laid out in Annex I to the regulation, the substance or mixture is hazardous.

A substance or mixture classified as hazardous and contained in packaging must be labelled with certain information, such as:

- the name, address and telephone number of the supplier(s);
- the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;
- product identifiers (such as its name and identification number);
- where applicable, and in accordance with the relevant provisions, hazard pictograms; signal words ("danger" or "warning"); hazard statements; and appropriate precautionary statements;
- where applicable, a section for supplementary information on its physical and/or health properties.

Packaging requirements in the CLP Regulation mirror those in existing law. Packaging containing hazardous substances or mixtures must, among other things:

- be designed and constructed so that its contents cannot escape;
- not be susceptible to damage by the contents; and
- be strong enough to withstand normal handling.

An outline of the new CLP Regulation, is available from: http://ec.europa.eu/enterprise/sectors/chemicals/files/ghs/clp_introduction_en.pdf.

Further details are available from the following European Commission websites:

- http://ec.europa.eu/enterprise/reach/ghs/index_en.htm;
- http://ec.europa.eu/environment/chemicals/index_en.htm.

Further details are also available from the ECHA website: http://echa.europa.eu/doc/publications

In addition, each Member State in the EU has a national helpdesk. Details can be found at http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks

D.2 Substances hazardous to health

Where, as in the manufacture of nanomaterials and nanotechnology-based products themselves, there is a risk of exposure to substances that might be hazardous to health, particular risk assessment requirements apply. A risk assessment is required when the substance is generated in the workplace and also where a substance is supplied to the workplace for use downstream. Where chemical substances are supplied, they should arrive appropriately classified or labelled and properly packaged in accordance with the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (see **D.1.2**).

The Control of Substances Hazardous to Health Regulations 2002 (COSHH) states that a substance will be considered hazardous to health if:

- it is classified as harmful, toxic, very toxic, irritant or corrosive (see CLP Regulation, Annex VI, Part 3, Table 3.2);
- it has an approved workplace exposure limit (WEL);
- it is present as a dust of any kind (not classified as above or has a WEL) at a concentration in air equal to or greater than 4 mg/m^3 (respirable fraction) or 10 mg/m^3 (inhalable fraction), as 8 hour time-weighted average values;
- it represents a risk to human health from its presence or the way it is used in the workplace.

It is the duty of employers to control exposure of employees and others to hazardous substances which might pose health threats.

COSHH adopts a risk assessment approach as the basis for managing the potential risks from such substances which might include nanomaterials and nanotechnology-based products. As part of this framework, an employer should:

- identify possible hazards and the risks posed by them;
- determine the necessary precautions;
- devise measures to prevent or control exposure;

- monitor and maintain these control measures;
- monitor exposures and conduct health surveillance;
- plan for accidents, incidents and emergencies; and
- train employees in these procedures and supervise their operation.

COSHH depends on data concerning the hazardous nature of materials, therefore, a problem might arise in relation to nanomaterials and nanotechnology-based products where there are uncertainties regarding the potential hazards which they pose. In accordance with the precautionary principle, lack of scientific certainty should not be a reason for postponing or foregoing sensible safety measures.

Advice on conducting risk assessments with a view to devising appropriate risk management procedures is contained in the BSI Guide to the safe handling and disposal of manufactured nanomaterials, PD 6699-2.

COSHH refers to workplace exposure limits (WELs) that are intended to protect employees from hazardous substances. However, currently, these limits are not drawn specifically by reference to substances at the nanoscale.

D.3 Dangerous substances and explosive atmospheres

Where there are any substances used or present at work that could, if not properly controlled, cause harm to people as a result of a fire or explosion, similar processes of risk assessment will be required but these are governed by the Dangerous Substances and Explosive Atmospheres Regulations 2002.

There is a concern that an increasing range of materials that are capable of producing explosive dust clouds are being produced as nanopowders and that too little is known about the potential explosion hazards of such materials.

Annex E (informative) Health and safety

E.1 General duties of health and safety at work

E.1.1 Workplace safety

Employers have long owed duties to take care of the health and safety of their employees. These duties are now embedded in section 2 of the Health and Safety at Work Act 1974. In particular, the employer must:

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);
b) ensure that the use, handling storage and transport of articles and substances is safe;
c) provide necessary information, instruction, training and supervision so that employees can carry out their jobs safely;
d) ensure that any workshop is safe and healthy with proper means of access and egress and with good housekeeping including the safe disposal of rubbish and the stacking of goods;
e) provide a safe working environment free from poisoning, gassing and diseases; and
f) provide adequate welfare facilities.

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. However this duty does not apply to very small organizations with five employees or fewer.

Where there is a recognized trade union, the employer should consult with any union safety representatives in order to establish and maintain high standards of safety. It might be necessary to form a safety committee where two or more safety representatives request this.

E.1.2 Duties to others

Duties under the Health and Safety at Work Act 1974 are not only owed to employees. There is a duty to the general public who ought not to be exposed to health and safety risks by the conduct of undertakings including the activities of self-employed persons. Similarly, owners of business premises should ensure safe access and egress to their premises. Where there are emissions from premises, those in charge of them must use the best practicable means for to prevent the escape of noxious or offensive fumes or dusts into the atmosphere.

E.1.3 Supply chain duties

Where nanomaterials and nanotechnology-based products incorporated into plant/equipment which is then supplied for use in the workplace, designers and manufacturers should research its safety when in use. On hand over of equipment, the installer will have particular responsibility for ensuring that the plant is safe to use. Anyone in that supply chain from the designer to the installer of plant will share responsibility for:

a) ensuring its safety during set up, use, cleaning or maintenance;
b) testing and examination to ensure its safety; and
c) providing adequate information concerning its safe setting, use, cleaning, maintenance, dismantling and disposal.

Where substances are supplied to be used in the workplace, manufacturers, importers and suppliers of substances for use at work, obligations to research and test the substance arise. Adequate information on safety must be provided and it will be necessary to ensure that during its proper use, handling, processing, storage or transportation that substance will be safe.

E.1.4 Duty of employees

Employees too face duties under the Health and Safety at Work Act 1974. While at work, every employee owes a duty of care for the health and safety of persons likely to be affected by their acts or omissions. As this also includes the employee, rules for personal safety can be demanded as part of terms of employment. Activities such as misusing plant and equipment are outlawed, making it quite possible to treat such activity as a disciplinary matter.

E.2 Specific duties of health and safety at work

E.2.1 Codes, standards and guidance

In addition to the general rules the Health and Safety at Work Act 1974 allows, many detailed regulations on particular workplaces or workplace hazards have been introduced by the Secretary of State. Such regulations can demand compliance with standards including British Standards. In addition, codes of practice, which again can include codes from bodies such as BSI, can be approved. An approved code of practice (ACOP) is not the same as a regulation since the latter has the force of law. Failure to follow a code is not itself a breach of the law, but a court might accept a code as laying down good practice. Therefore if an employer has failed to follow a code, it will be difficult for that employer to show that it did all that was reasonably practicable to prevent an accident.

E.2.2 Best practicable means

Many duties in Health and Safety at Work Act 1974 are not absolute but are instead a requirement to act "so far as is reasonably practicable" or to use "best practicable means". Following codes and guidance is one of the simplest ways of demonstrating that an employer has taken reasonable and practicable steps. There is, for example, an Approved Code of Practice on how to conduct risk assessments (see **C.3**).

There are also many examples of particular duties arising out of regulations, such as for:

- ventilation, heating, lighting and workstations through the Workplace (Health, Safety and Welfare) Regulations 1992 (see **A.1.6**);
- protective equipment for employees through the Personal Protective Equipment at Work Regulations 2002 (see **A.1.8**); and
- reporting of industrial injuries and disease through the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013.

E.2.3 Employers' liability insurance

It is a duty of all employers with employees based in England, Scotland or Wales to take out employers' liability insurance to cover the cost of injuries or illness suffered by employees and arising out of their employment.

E.3 Management of health and safety

The starting point for good occupational health and safety is a well-conducted risk assessment. The Management of Health and Safety at Work Regulations 1999 contain more explicit requirements on employers to help manage health and safety in line with the Health and Safety at Work Act 1974. In particular, employers must carry out a risk assessment and if there are five or more employees a record should be made of significant findings of the risk assessment.

In addition to conducting the risk assessment, employers must also:

a) make arrangements for implementing the health and safety measures in accordance with findings from the risk assessment;
b) appoint competent people to help implement the measures;
c) set up emergency procedures;
d) provide information and training to employees; and
e) cooperate with any other employers sharing the same workplace.

More information on this is available in the HSE leaflet Five Steps to Risk Assessment available at http://www.hse.gov.uk/pubns/indg163.pdf.

E.4 Common law duties

In addition to having to the duties under health and safety regulation, there are also duties placed upon employers in common law (for example under the employment contract or in the law of negligence). These are very similar indeed but employees can sue if injured in the course of their work where employers have failed in these duties. The primary duties are:

a) to provide and maintain a safe place of work;
b) to provide and maintain safe plant and equipment;
c) to provide and maintain safe systems of work; and
d) to provide co-employees competent to carry out their duties safely.

The employer owes a duty of reasonable care to employees and anyone else likely to be affected by their activities. Part of the common law duty is to comply with the statutory duties in health and safety regulation (above) and the employer can often be sued for breaching these duties. Liability to pay damages will arise where death or personal injury results from foreseeable risks unless the employer has taken all practicable precautions to eliminate such risk.

The employer's duty of care is that of a reasonable and prudent employer. This is an objective standard and it assumes that a reasonable employer will do what is reasonable to keep up with developments in the industrial sector and act accordingly. An employer failing to meet this standard will be regarded as negligent. The employer may bear liability for the acts of co-workers (vicarious liability) where their actions cause injury to others.

In order to recover damages the burden will be on the employee to show that:

- the employer owed a duty of care;
- the employer breached that duty; and
- as a result of the breach the employee suffered injury or disease.

E.5 Laboratory health and safety

The general law relating to health and safety at work is given in Annex C, which covers manufacturing. All laws referenced in **E.1** to **E.4** apply to persons employed in a laboratory setting and/or undertaking research and development as part of their employment.

HSE recommends adopting a precautionary approach to the risk management of all nanomaterials. Advice from the HSE in relation to using nanomaterials at work is available from: http://www.hse.gov.uk/pubns/books/hsg272.pdf

Strategies to control exposure to nanoparticles may include:

- total enclosure of the process;
- partial enclosure with local exhaust ventilation;
- local exhaust ventilation;
- general ventilation;
- limitation of numbers of workers and exclusion of others;
- reduction in periods of exposure;
- regular cleaning of wall and other surfaces;
- use of suitable personal protective equipment; and
- prohibition of eating and drinking in contaminated areas.

Annex F (informative) Consumer safety

F.1 Product safety

F.1.1 General product safety

The General Product Safety Directive (Directive 2001/95/EC on general product safety) provides a common standard for product safety and consumer protection across Europe. Products intended for consumer use shall only be placed on the European market if they are "safe". "Products" here has a wide ranging definition covering all goods that placed on the market, or supplied or made available to consumers for their private use. "Placing on the market" is a concept wider than sale so that it can include, for example, leasing or hiring out goods. In consequence any nanomaterials and nanotechnology-based products in circulation must be safe. In the UK the requirements of the Directive are to be found in the General Product Safety Regulations 2005 which came into force on 1 October 2005.

There are certain directives which cover specific products on the market (such as cosmetics or toys) and where their specific requirements override the more general notion of "safe" products in the General Product Safety Directive. In this way, the Directive acts as a safety net to ensure that all products offer a reasonable standard of consumer protection. If you are unsure whether specific or general requirements apply to your product consult the Commission Guidance which is available from: http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm#sect

F.1.2 Obligations on producers and distributors

Producers are obliged to place only safe products on the market. A producer here will include both a manufacturer of the product and also the first importer of the product into the European market such as a UK distributor of a south east Asian product that contains nanomaterials. The notion of "producer" can also include someone reconditioning or customizing a product.

Producers must provide consumer information to allow the assessment of risks inherent of their products. Products must be monitored for the identification of possible risks. If a producer recognizes that a product is "unsafe" the relevant authorities must be informed without delay. It will be necessary to work with the authorities and take appropriate action including, where necessary, product recall.

Distributors are charged with "due care" in ensuring compliance with product safety rules. They too must monitor products and cooperate with both producers and authorities.

F.1.3 The concept of safety

A product may be considered "safe" if its use under normal or reasonably foreseeable circumstances presents no risk or a minimum risk compatible with its use, providing always that this is consistent with a high level of consumer protection. In assessing the safety of a product a number of factors will be taken into account including:

a) the characteristics of the product;
b) its packaging and any instructions for assembly, maintenance, use and disposal;
c) labelling and other information provided for the consumer; and
d) the types of consumers at risk when using the product, such as children or the elderly.

As with product liability (below) the existence or availability of safer products posing less risk will not necessarily mean that a product is unsafe.

The regulations do not apply to products used by workers in the workplace. Health and Safety at Work regulation governs the safety of such products and equipment. Because only use by consumers is covered, products used in the provision of a service (e.g. hair styling), even if used on a consumer of that service, lay outside the scope of the regulations.

F.1.4 The importance of standards

Where there are national laws governing the risk attaching to specific products, products conforming to such rules will be safe products for the purposes of the Directive. Even if neither a specific regulation nor a national safety law applies to the product, account might be taken of standards to assess safety including:

a) voluntary European standards;
b) European technical specifications;
c) national standards such as a BSI standard with no European equivalent; and
d) an industry code of practice.

Note that conformity to such a standard will not necessarily render a product safe because, for example, the standard was never intended to govern the particular risk posed by the product. Moreover even if a product conforms to a standard, regulatory authorities can take action (see below) where a conforming product is shown nonetheless to be unsafe.

F.1.5 Enforcement

Authorities have the power to order remedial action and to impose penalties in case of non-compliance. If no voluntary action is taken to ward off the danger, they can either order such action to be taken or organize remedial measures themselves. However, where the producer becomes aware that a product on the market is unsafe, it must immediately inform the competent authorities. Immediately here means:

a) if investigations are continuing – within 10 days;
b) where a serious risk is apparent – within 3 days; and
c) in an emergency – Immediately, by the fastest means.

The authorities will then inform the EU Commission of the measures taken. This information will be circulated to the product safety authorities of other Member States. There is a rapid exchange system, RAPEX, to cope with serious product defects.

The appropriate authority varies in accordance with the type of product. For example, medical devices will be regulated by the Medicines and Healthcare Products Regulatory Agency. There is no particular regulator for nanomaterials and nanotechnology-based products. It is the type of product that will determine regulatory responsibility so that (for example) the Food Standards Agency is charged with ensuring that food is safe.

However, for many products in common usage, the principal enforcement responsibility will fall upon the Local Authority in which the company under investigation has its headquarters. Enforcement will usually fall upon their Trading Standards Departments in England, Wales and Scotland, or in Northern Ireland through District Council Environmental Health Officers. In order to enforce the regulation, appropriate authorities have the powers to enter premises (by warrant if necessary), make test purchases and undertake testing, and seize records and products from producers and distributors.

Such authorities are armed with significant powers including:

a) imposition of warnings – demanding that the product carries a warning of its risk;
b) suspension notices – suspending the supply of the product;
c) withdrawal notices – preventing further supply;
d) recall notices – demanding recall of the product from the market; and
e) forfeiture and destruction – to eliminate dangerous products.

Contravening such notices constitutes a criminal offence but it is an offence in any case for a producer to place a product on the market unless it is safe.

F.1.6 Avoiding unsafe products

No one aims to place an unsafe product on the market but hindsight gained from regulatory interventions demonstrates that there are a series of errors into which companies might fall. The following shortfalls are common:

- insufficient research and testing;
- failure to modify product in the face of risk;
- failure to attach warnings or appropriate instructions to cover inherent risk;
- non-compliance with relevant industry standards or regulatory requirements; and
- lack of communication with the regulators.

Note that the present state of development of nanotechnology itself gives rise to uncertainty given the lack of experience of certain products containing nanomaterials. Present difficulties include:

- lack of regulation and standards for nanomaterials and nanotechnology-based products;
- rapidly evolving scientific knowledge;
- room for potential latent or undetected hazards; and
- the possibility of claims based on defective design.

For assistance in gauging the risk caused by a product see the PROSAFE guidelines, which are available from: http://ec.europa.eu/consumers/safety/committees/ra_guidelines_workshop11122007.pdf

F.1.7 Sensible precautions

If there are difficulties with a product early action might be vital. It is possible to cut down the room for error and guard against incidents by good internal procedures including:

- a strong emphasis on quality assurance;
- agreements in contractual documentation as to which parties in the supply chain will bear the risk of and responsibility for products shown to be unsafe;
- continual benchmarking against relevant industry standards;
- tracking of complaints by within the supply chain or on the part of consumers; and
- clear tracking of batches of materials (e.g. carbon nanotubes) and products to facilitate recall if necessary.

It makes sense to plan for how the discovery of an unsafe feature of a product will be handled. Among the issues to consider here are:

- contractual responsibilities;
- insurance;
- knowledge of appropriate regulators; and
- an effective communication strategy.

Failure to plan for contingencies in relation to the supply of nanomaterials or nanotechnology-based products might make it difficult to respond to incidents, heightening risk to consumers of the product and opening the way to legal liability for injury or damage caused by these materials. The potential for liability is now considered.

F.2 Product liability

F.2.1 Strict liability for damage

Consumers injured by defective products might be able to sue for damages on a strict liability basis. This means that there is no need to prove negligence on the part of the manufacturer. If the product is unsafe and causes injury then the injured person (whether or not they bought the product themselves) can sue for compensation. The consumer need only prove that the defective product caused the injury. This is true throughout the European Union because this form of strict product liability was introduced by a European Directive – see Product Liability Directive (85/374/EEC) introduced in the UK with effect from 1 May 1988 by the Consumer Protection Act 1987.

The consumer can sue for death or personal injury but also for the loss or damage to other property. There is a minimum level of claim of £275 for damage to private property but thereafter damages under the Act are unlimited. A claim must be made within three years of the date of injury or damage or the date on which the injury or damage was known to the claimant. However any right to sue is lost where more than ten years have passed since the defective product was supplied by the producer. Also the damages awarded to a consumer might be reduced where it can be shown that carelessness (contributory negligence) on the part of the consumer in part caused the injury.

F.2.2 Potentially liable parties

There are a number of parties in the supply chain which might face liability for the consumer's injuries. The consumer will have a choice of which party to sue and can sue more than one party. It is not possible to exclude the right to sue under the regulation when supplying goods. The potentially liable parties include the following (using the language used in the regulation).

a) The Producer – this is normally the manufacturer but the notion of a "producer" is rather wider to include a person supplying raw materials or a person processing a product (such as a foodstuff). A company packaging goods would not normally be considered a "producer" unless the packaging fundamentally changes the characteristics of the item supplied.

b) The Importer – If the producer resides outside of the European Community the consumer might face difficulty in recovering damages. Therefore the law allows the consumer to sue the party first importing the goods into the European market. This means that where goods are imported into the UK but then dispatched for sale in another member state of the EC, it is the UK importer, as first importer into the EC that will face liability and not the seller elsewhere in Europe.

c) Own-branders – This term refers to suppliers who attach their name to a product and give the impression that they are the producers (as with supermarket "own brand" goods. In contrast wholesalers, retailers and other suppliers are not ordinarily liable but they might attract liability if they refuse to identify the producer, importer or "own-brander" at the request of an injured party.

F.2.3 Product defects

A product is defective where the safety of the product is not such as persons generally are entitled to expect. Thus the test for a defect is objective being based on a general expectation. This also means that poor quality as such might not lead to liability if expectations of the product are low even if there are safer versions of the same product on the market. This definition also incorporates the notion that the expected reasonable use of the product is significant and a producer or importer of a product can shape such expectations, for example through the instructions supplied with the product.

The court will decide the question of whether goods are defective and will take into account various factors including:

a) the background to the supply;
b) the intended use of the product;
c) the reasonableness of the actual use made of the product;
d) marketing literature; and
e) warnings.

All consumer goods including foodstuffs and all goods used at a place of work are covered by this regulation. All components and raw materials are covered so although a building is not covered as such, a building product containing nanomaterials, for example, is subject to strict product liability. If a component is fitted into another product, an injured party might have the right to sue both the component manufacturer and the producer of the finished product.

F.2.4 Defences

There are a number of defences open to a producer or importer. The most obvious one is to deny the supply of the product. This might be because, for example, the company was not the first importer into the European market as some other company imported the goods. Similarly, it is open to the producer to prove that the goods were not defective at the time of supply. An example might be where careless storage by a seller has caused the defect in the goods.

There are certain defences that might be particularly important in the context of nanomaterials and nanotechnology-based products. These are as follows.

a) There is a "development risk" defence to take account of scientific knowledge at the time that the product was supplied. There will be no liability where the state of scientific and technical knowledge at the time of supply of the product was not such that "a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in their products while they were under their control".
b) There is also a defence if the defect was caused by complying with the law but, in order to take advantage of this defence, it is necessary to prove that the defect inevitably resulted from compliance with regulation.
c) Finally, the producer of a component will not be liable where the defect arises out of the inadequate specifications of the manufacturer or design of the finished product.

F.2.5 Avoiding product liability

There are certain steps that a company can take to manage the risks of liability claims. These include:

a) clear allocation of responsibility for possible product defects in commercial contracts covering issues of supply and distribution;
b) a good knowledge of regulation and standards and a strong culture of compliance;
c) careful attention to marketing literature and to instructions and warnings accompanying the product; and
d) appropriate and sufficient liability insurance coverage.

Annex G (informative) Environment protection

G.1 Environmental permitting (England and Wales)

G.1.1 General

Under the Environmental Permitting Regulations 2007, a new system of controlling polluting activities was introduced. The regulations combined a number of individual pieces of regulation (Integrated Pollution and Prevention Control Regulations and Waste Licensing Regulations) into one combined regulation. The purpose of the permitting scheme is to ensure that authorized activities do not cause harm to the environment or endanger human health.

G.1.2 Who does it apply to?

Listed below are some of the activities, which require an environmental permit where they meet the required activity threshold prescribed in the regulations:

- energy;
- production and processing of metals;
- manufacturing glass and glass fibre;
- ceramic production;
- the chemical industry;
- plant health products and biocides;
- the storage of chemicals in bulk;
- paper, pulp and board manufacturing activities;
- coating activities, printing and textile treatments;
- the manufacture of dyestuffs, printing ink and coating materials;
- the treatment of animal and vegetable matter and food industries; and
- SED activities.

G.1.3 Requirements of environmental permitting

If the activities of a company are captured under the Environmental Permitting regime, they will not be able to operate unless an environmental permit has been obtained from the Environment Agency. A permit application must include an assessment of environmental risks of the proposed activities.

The Environment Agency must be satisfied that the assessment is sufficiently robust and that adequate control measures have been put in place before a permit will be granted. If a permit is granted, the Agency can impose certain conditions (e.g. safety conditions) on the applicant company which must be fulfilled.

Waste production is avoided and where waste is produced, it is sent for recovery (reuse, recycling or recovered for energy), or where this is not technically or economically feasible, it must be disposed in a way, which avoids or reduces any impact on the environment.

The operator of the activity must show that waste is being managed in a proper manner.

G.1.4 Discharge consents

If you want to discharge trade effluent directly into surface water (such as rivers, streams, and canals) you will likely need to apply for a discharge consent from the Environment Agency under Schedule 10 of the Water Resources Act 1991. Trade effluent is any liquid waste (effluent) that is discharged from premises being used for a business, trade or industry. Guidance on how to apply for a discharge consent is available from: http://www.environment-agency.gov.uk/business/topics/water/

In addition, you might also need a trade effluent consent or agreement if you allow the discharge of any trade effluent into a public sewer. These agreements are made with your local water and sewerage company. You can find your local company at: http://www.water.org.uk/home/resources-and-links/links/water-operators/sewerage-operators?lang=_e

G.1.5 Groundwater regulations permits

A permit is required under the Groundwater Regulations 1998 if you cause or allow the discharge of any "listed substance", where such discharge might lead to its introduction into groundwater (i.e. water below the soil, but in contact with the soil). "Listed substances" include silver, lead and nickel, among others.

The regulations do not apply to any discharge containing a quantity and concentration of listed substances found by the Environment Agency to be "so small as to obviate any present or future danger of deterioration in the quality of the receiving water". However, what is "so small as to obviate any" danger is not defined and the regulations make no specific reference to nanomaterials or nanotechnology-based products.

Detailed guidance on the regulations is available from: http://archive.defra.gov.uk/environment/quality/water/waterquality/ground/documents/groundwater-guidance.pdf

G.1.6 Regulated activities

Under the Environmental Permitting (England and Wales) Regulations 2007, an environmental permit is required in order to operate a "regulated facility". Plant which comes under the definition of "regulated facility" include sites where the following "listed activities" take place: the manufacturing and the processing of metals and the manufacturing of chemicals and pharmaceuticals.

"Listed activities" are split into three categories: part A(1), part A(2) and part B. Part A permits control activities with a range of environmental impacts (including emissions to air, land and water) and part B permits control activities which only cause emissions to air. Depending on which activities take place at your plant, either the Environment Agency or the local authority will be your regulator (with local authorities dealing with smaller, less complicated sites).

If planning permission is also required for a facility, it is recommended that the application for an environmental permit is made at the same time. Otherwise, the environmental permit must be obtained before the "listed activities" take place for the first time.

If you are unsure whether or not you need an environmental permit, detailed guidance is available from: http://archive.defra.gov.uk/environment/policy/permits/guidance.htm

G.1.7 Pollution prevention and control permits (Northern Ireland and Scotland)

Because the environmental permitting regime applies only in England and Wales, references to environmental permits should be read as pollution prevention and control permits (PPC) in Northern Ireland and Scotland.

G.1.8 Waste management licences (Northern Ireland and Scotland)

Waste management licences are now environmental permits under the environmental permitting regime in England and Wales, but in Northern Ireland and Scotland, separate waste licences (or exemptions) are required for waste management activities.

G.1.9 Water quality

The Water Resources Act 1991 makes it a criminal offence to cause or allow any "poisonous, noxious or polluting matter" to enter any "controlled waters" (a wide definition that includes rivers, coastal waters and inland freshwaters). The offence here is not caused where the quality of the water is affected. Instead, you commit the offence whenever the matter enters the water (whether or not it then causes any harm). There might be doubts whether the release of nanoparticles to water might be considered "poisonous" or "noxious" for the purposes of this offence, but the word "polluting" is widely drawn and nanoparticles might well be taken to be polluting. It is a defence, however, if the discharge of such substances to water is covered by a discharge consent (see **G.1.4**)

Where there is entry into controlled waters, the Environment Agency has powers under The Water Resources Act 1991 to require polluters to remove or reduce such matter and remedy any damage that has occurred. In addition, there are specific laws dealing with particular types of water sources and polluting matter, such as the Groundwater Regulations 1998, which prohibit the entry of "listed" substances, including mercury and cadmium, into groundwater. On the whole these listed substances do not differentiate between conventional substances and those at the nanoscale.

G.2 Environmental damage prevention and remediation

More widely, the Environmental Damage (Prevention and Remediation) Regulations 1999 aim to make polluters liable where they cause significant impacts on the environment. The regulations only cover the most serious cases and cover:

a) serious damage to surface or ground water;
b) contamination of land where there is a significant risk to human health; and
c) serious damage to EU protected natural habitats and species or damage to sites of special scientific interest (SSSI).

The Environment Agency, Natural England, local councils and the Secretary of State are responsible for administering and enforcing the regulations, depending on the type of damage involved. Liability might occur without any need for the regulator to show fault or negligence. Where damage is caused, the polluter must notify the regulator and then takes steps to undertake remediation and prevent any further damage occurring. Detailed guidance on the regulations is available from: https://www.gov.uk/government/publications/environmental-damage-prevention-and-remediation-regulations-2009-guidance-for-england-and-wales

G.3 Waste duty of care

G.3.1 Content of the duty of care

Anyone who produces or imports, keeps or stores, transports, treats or disposes of waste is under a duty of care to take all reasonable steps to ensure that all of the waste that their company produces is disposed of in a safe and secure manner. This is covered under The Environment Protection Act 1990 and the Environmental Protection Act (Duty of Care) Regulations 1991. The duty also applies to anyone employed as a broker.

The objective of the Duty of Care is to ensure that all waste is managed correctly from the place where it is produced to the point of final disposal. It places a responsibility on the waste producer to know what happens to their waste.

A definition of waste is given in Table G.1.

Table G.1 – Definition of waste

The Waste Framework Directive 2008/98/EC, defines waste as:

- Waste means any substance or object which the holder discards or intends or is required to discard.
- Waste holder means the waste producer or the natural or legal person who is in possession of the waste.
- Waste producer means anyone whose activities produce waste (original waste producer) or anyone who carries out pre-processing, mixing or other operations resulting in a change in the nature or composition of this waste.

G.3.2 Content of the duty of care

The law says a waste producer must stop any waste they have produced escaping from their control. The producer must store it safely and securely and prevent it causing pollution or harm to anyone in the following ways:

a) ensure that the waste is secure by for example keeping it in a suitable container;

b) if waste is passed onto someone else, check they have authority to take it. The law says the person to whom you give your waste must be authorized to take it. You must make sure the contractor you employ is a Registered Waste Carrier (they must be able to show you a certificate of registration). Details can be confirmed with the Environment Agency. If they are not registered, check whether they are exempt from registration, again these details can be confirmed with the Environment Agency;

c) complete a Waste Transfer Note and keep a copy of this transfer note on file for two years. This document gives details of the types and quantities of waste to be collected from your premises and also gives details of who collects it and how it is disposed of or who it is transferred to. When completing the transfer note, was must be described in writing by using the European referencing system (European Waste Catalogue), which is provided in the *List of Waste Regulations 2005.*

For each type of waste that is collected; a separate Waste Transfer Note will need to be completed.

G.3.3 Classifying wastes containing nanomaterials or nanotechnology-based products

The European Waste Catalogue is divided into twenty main chapters, most of which are industry-based but some of which are based on materials and processes. Hazardous wastes are signified by entries where the code is followed by an asterisk. There are no specific codes in the List of Wastes for nanomaterials or nanotechnology-based products, therefore the bulk-scale code has to be used.

When describing waste, which contains nanomaterials or consists of nanotechnology-based products, you must identify in the first instance the source generating the waste. If the material is for example chemicals, codes for chemicals can be found under either chapter 06 (inorganic chemical processes) or chapter 07 (organic chemical processes) or it might be under chapter 11 (wastes from chemical surface treatment and coating of metals and other materials; non-ferrous hydro-metallurgy). If the appropriate code cannot be found in these chapters, the remaining chapters in the Catalogue which deal with product type (oil, packaging, etc.) will need to be examined.

To ensure further the proper disposal of nanomaterials and nanotechnology-based products, producers should consider what disposal method will result in the least amount of damage to human health and the environment.

G.3.4 Enforcement

Breach of the Duty of Care is an offence, with a penalty of up to £5 000 on summary conviction or an unlimited fine on conviction on indictment.

Further information is available from:

- Stationery Office, "Waste Management, The Duty of Care, A Code of Practice", ISBN 0-11-753210-X http://archive.defra.gov.uk/environment/waste/controls/documents/waste-man-duty-code.pdf

- Landfill Directive and Regulatory Guidance Note 14 (version 2.4), The Duty of Care and the European Waste Catalogue http://www.environment-agency.gov.uk/static/documents/Business/lfdrgn_14_v2.4august.pdf

G.3.5 Waste disposal

All materials and products eventually come to the end of their useful life, including those made with nanotechnologies. Nanomaterials and nanotechnology-based products will ultimately enter the waste stream and find their way into the waste management regime, either by recovery, incineration or landfill – and eventually into the air, soil and water. As a result, it is important to consider how various forms of nanomaterials and nanotechnology-based products will be disposed of and treated at the end of their use.

There are a wide category of regulation that covers the obligations of actors in the waste chain and sets out waste management options and targets. None of the current waste regulation in the UK includes any specific requirements for items at the nanoscale or for products/materials produced as a result of nanotechnologies. As a result, the same requirements under waste regulation apply to products/materials that are produced as a result of nanotechnologies or conventional manufacturing methods.

Key requirements of waste disposal under the Landfill Directive include:

- liquid wastes are banned from landfill;
- waste must be sent to the correct landfill site, hazardous to hazardous landfill, non-hazardous to non-hazardous landfill and inert to an inert landfill;
- waste must be treated before it can be landfilled; and
- hazardous waste with a total organic carbon (TOC) content of more than six per cent is no longer accepted for landfill.

G.4 Hazardous waste

G.4.1 What is hazardous waste?

The Hazardous Waste Regulations 2005 set out the rules for assessing if a waste is hazardous or not. These regulations also refer to the List of Waste Regulations 2005 (known at EC level as the European Waste Catalogue) as a means of determining whether a waste is hazardous. There are no special provisions in the Hazardous Waste Regulations relating to nanomaterials or nanotechnology-based products. The List of Wastes makes no distinct between substances at the conventional and at the nanoscale.

Under the Hazardous Waste Regulations, it is an offence to produce hazardous waste at premises, or remove that waste from premises, unless those premises are either registered with the Environment Agency or are exempt. All types of premises that produce hazardous waste are exempt from registration if no more than 500 kg of hazardous waste is produced in a year.

It is the responsibility of the producer to identity whether they produce hazardous waste. Consequently, all producers must know the composition of the waste they produce.

Waste is hazardous if:

a) in the List of Waste Regulations, the waste code is followed by an asterisk (for example fluorescent tubes, lead acid batteries). Wastes without an asterisk are not hazardous;

b) some of the hazardous wastes in the list are classed as "absolute" hazardous waste, which means that no matter the circumstances the waste will always be hazardous. Subsequently, if a material is an absolute hazardous waste at the bulk scale, it will be an absolute hazardous waste at the nanoscale;other wastes might be hazardous or not depending whether it contains "dangerous substances" at or above certain levels, these are classed as "mirror" hazardous wastes. In the List of Wastes, these wastes can be recognized as they are covered by linked entries, one with an asterisk, the other without;

c) there are three ways to find out if the substances marked as a "mirror" entry waste are dangerous:

   1) use the approved supply list (ASL). This shows hazard information and classification for many common chemicals. If the waste contains substances listed in the ASL, this classification **must** be used;

   2) obtain data from reliable data sources such as reference books or the internet. These sources must be "peer reviewed". That means that other professionals have looked at and approved the data. With this data, use the methodology given in the Approved Guide to the Classification and Labelling of Substances and Preparations for Supply to determine the appropriate classification;

   3) Use information from the safety data sheets or other data sources to find out whether the waste contains dangerous substances;

d) if the producer does not know the composition of the waste, the waste will need to be tested for any hazardous properties H1 to H14. There are

two ways to find out if "mirror" entry waste has a hazardous property:

1) where the waste contains "dangerous substances", their concentrations (that is the levels they are present at in the waste) are compared against the appropriate thresholds; or
2) a test is carried out to find out if the waste has a hazardous property;

e) there might be occasions when the Secretary of State for the Environment assigns a particular waste type as hazardous, where under normal circumstances it would not be so classified.

It follows that producers of nanomaterials and nanotechnology-based products will need to know the composition of their products to enable them to identify whether the product should be classed as hazardous or not.

G.4.2 Managing hazardous waste

The Hazardous Waste Regulations introduced a number of requirements, which must be adhered to when dealing with hazardous waste.

a) The mixing of hazardous waste with any other non-hazardous waste or any different category of hazardous waste is banned unless mixed under an Environmental Permit.
b) It is an offence to fail to comply with the different requirements of the Regulations, for example:
   1) failure to notify premises;
   2) removing hazardous waste without a consignment note.
c) All hazardous wastes must be handled, stored and consigned in a manner consistent with maximum risk reduction in terms of accidental release and harm to persons or the environment.
d) As soon as any hazardous substance becomes waste it should be properly contained and labelled with its name, description and EWC code(s).
e) A duty is also placed on the holder to separate mixed waste where technically and economically feasible.

In addition, under the Landfill Regulations, if hazardous waste is to be disposed to landfill, it must be sent to a designated hazardous landfill site.

G.5 Producer responsibility

G.5.1 Concept of producer responsibility

Producer responsibility in the UK is an extension of the "polluter pays" principle, and is aimed at ensuring that businesses who place products on the market take responsibility for those products once they have reached the end of their life.

The concept behind producer responsibility applies equally to nanomaterials and nanotechnology-based products, requiring producers or manufacturers to minimize human and environmental exposure to free nanoparticles at all stages of the life cycle and should also form an integral part of the innovation and design process. Integral to the concept of producer responsibility is that waste management is seen as part of the product life cycle.

G.5.2 What products are covered?

In Europe there are schemes in place for:

- packaging and packaging waste;
- end of life vehicles;
- waste electrical and electronic equipment; and
- batteries.

G.5.3 Packaging

The European Directive 94/62/EC on Packaging and Packaging Waste seeks to harmonize the management of packaging waste in the EU and reduce the impact of packaging and packaging waste have on the environment. The main objective is to increase the recovery and recycling of packaging waste in a consistent way in all Member States of the EU but priority is also given to reducing the amount of packaging used and the reuse of packaging. Inclusion in obligations under the UK regulations [The Producer Responsibility Obligations (Packaging Waste) Regulations 2005] depends on the bulk of the materials handled or the turnover of the business and is not dependent on the content of the packaging. As such it has no direct application to nanomaterials used in packaging.

G.5.4 End of life vehicles (ELV)

The End of Life Vehicles Regulations 2005 requires that all ELVs are only treated by authorized dismantlers. The regulations place a concentration on reuse, recovery and recycling as the preferred disposal means. The regulations require that producers limit the use of hazardous substances and increase the quantity of recycled material used in the manufacture of their vehicles; and that producers design vehicles for easy recycling. In addition, hazardous materials are removed before a vehicle is dismantled, which is defined as any substance which is considered to be dangerous under Directive on Dangerous Substances and as such on the approved supply list.

Note the present state of classification of nanomaterials and nanotechnology-based products as a new

substance or as an existing substance, might cause uncertainties for producers. Where nanomaterials are currently not identified as hazardous under the Directive on Dangerous Substances or on the approved supply list, reference might need to be made to the status of these products at the bulk scale. However, with the improvement of knowledge and information there might come a time when these nanomaterials might be classed as hazardous.

G.5.5 Waste electrical and electronic equipment regulations (WEEE)

The regulation aims to reduce the amount of WEEE disposed to landfill by reducing the amount of WEEE produced, encouraging reuse and recycling by encouraging its separate collection and subsequent treatment. It also aims to improve the environmental performance of producers by encouraging a life cycle approach to the production of electrical and electronic equipment, including placing the responsibility of reuse and recycling on the producer.

The regulations have a number of implications for producers and distributors (retailers) of EEE.

The regulations apply to all EEE put on the UK market, which falls within one of the ten categories listed in Schedule 1.

If you import, rebrand or manufacture EEE in the UK you should have been registered with an approved producer compliance scheme.

If you are an importer, rebrander or manufacturer and fall under the WEEE Regulations it is necessary to join a producer compliance scheme, provide information on how to dismantle and recycle your products when they come to the end of their life, mark all new electrical products with:

- the crossed-out wheeled bin symbol;
- a producer identification mark; and
- a date mark.

G.5.6 Batteries

The Waste Batteries and Accumulators Regulations 2009 set out new rules for the collection, treatment and recycling of all types of batteries and accumulators. The regulations place certain new responsibilities on producers, sellers, distributors, waste treatment sites and waste battery exporters.

If you import, manufacture, and/or sell portable batteries in the UK, then you might have obligations under the new regulations.

A producer is someone who puts products containing batteries onto the UK market for the first time rather than , for example, having bought the batteries from another UK supplier.

- Small producers need to register with the National Packaging Waste Database, within four weeks of the first date on which you first place any batteries on the UK market. You will need to provide data on the amount of portable batteries placed onto the market over a calendar year.
- Large producers need to join a battery compliance scheme, which will enable the producer to pay for the collection, treatment and recycling of waste batteries in proportion to their market share. In addition, the producer will need to keep a record of the weight of portable batteries placed onto the market.
- Industrial and automotive producers need to register with the NPWD, within four weeks of the first date on which they first place any batteries on the UK market. They must provide information to BIS showing the total amount in tonnes of industrial and/or automotive batteries placed on the market in the relevant compliance period. They must also report the total amount in tonnes of waste industrial and/or automotive batteries they have been responsible for taking back or collecting, and which they have been responsible for delivering to an approved battery treatment operator (ABTO) or an approved battery exporter (ABE).

Annex H (informative) Regulated products

H.1 General

Many types of product require some form of regulatory approval before they can be placed on the market. This annex covers the approval process for various nanomaterials and nanotechnology-based products. In general, the approval process will have nothing to say that relates particularly to nanomaterials and nanotechnology-based products but there are exceptions as in the case of cosmetics. Where the regulation is silent as to its application to nanomaterials and nanotechnology-based products, it will be necessary to determine whether the regulation for that product type is likely to demand disclosure of the presence of nanomaterials before a product is placed on the market.

In this annex we cover the following product types:

a) biocidal products;
b) cosmetic products;
c) detergents;
d) electrical equipment;
e) fertilizers;
f) food;
g) medicinal products;
h) pesticides; and
i) plant protection products.

H.2 Biocidal products

H.2.1 General

The EU Biocidal Products Regulation (EU) No 528/2012 defines a biocidal product as:

> "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action"; or
>
> "any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action".

In practice, this means that a diverse group of products, including disinfectants (for home and industrial use), preservatives (for manufactured and natural products) and pest control products, fall within the definition of biocidal product. To check if a product falls within the definition, see Annex V of the regulation. Certain products are excluded from the definition such as those covered by other specified EU legislation (e.g. products covered by legislation on medicinal products, veterinary medicinal products). For a list of exempting legislation, see Article 2(2) of the regulation.

H.2.2 EU list of approved active substances

A biocidal product cannot be placed on the EU market without authorization. Authorization can only be obtained if the active substance contained in that biocidal product has been approved under the regulation. The list of approved active substances is contained in Article 9 of the regulation.

Companies wishing to place a biocidal product on the market containing an active substance that has not yet been approved under the regulation (i.e. it is not listed in Regulation 9) must first submit an application to the European Chemical Agency. For details, see the HSE's website on Active Substance Approval.

The regulation imposes certain conditions on approval (see Article 4). One condition is that the approval of an active substance shall not cover nanomaterials except where explicitly mentioned [see Article 4(4)]. This means that active substances listed as approved in Regulation 9 shall not include nanomaterial variants of those substances, unless specifically stated in the approved list.

For the purposes of the regulation, nanomaterial means a natural or manufactured active substance or non-active substance 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 to 100) nm [see Article 3(1)(z)].

H.2.3 National authorization

Companies wishing to place a biocidal product containing an approved active substance on the UK market must obtain authorization from the HSE (the UK's Competent Authority for biocides). Details of the application process can be found on the HSE's

website on the authorisation process. Applications for authorization must be submitted via the European Chemical's Agency's R4BP system.

Certain biocidal products qualify for the simplified authorization procedure, which reflects the principle that once an active substance has been authorized in one Member State, it can be freely marketed within the EU provided the Member State is notified before the active substance is placed on the market and no objections are raised by the other Member States (see Articles 19 and 25).

Biocidal products containing nanomaterials do not qualify for the simplified authorization procedure [see Article 25(c)].

Companies wishing to place a biocidal product containing nanomaterials on the market are required to submit additional information as part of the authorization procedure (see Article 19). One condition imposed is that authorization shall not be granted unless, where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately [see Article 19(1)(f)].

Once authorized, biocidal products must conform to certain other requirements of market entry. Companies responsible for placing a biocidal product on the market must ensure the product label provides certain information (see Article 58). The label must include, among other things, the name of all nanomaterials contained in the biocidal product, followed by the word "nano" in brackets [see Article 58(3)(d)], and information on any specific related risks [see Article 69(2)(b)].

H.2.4 Overlap with non-agricultural pesticides legislation

Certain biocidal products (specifically, non-agricultural pesticides) also fall within the remit of the Control of Pesticides Regulations (COPR) 1986. Non-agricultural pesticides (e.g. wood preservatives, public hygiene insecticides, some repellents and other vertebrate control agents) will be required to conform to the COPR. These require prior approval before being advertised, sold, supplied, stored or used in the UK. The HSE manages all approval applications.

H.3 Cosmetic products

H.3.1 General

Regulation (EC) No 1223/2009 defines a "cosmetic product" as:

> "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours".

H.3.2 Notification

Before placing a cosmetic product on the market, the responsible person must ensure that the product is safe. To demonstrate safety, the product must undergo a safety assessment (see Article 10) conducted by a qualified individual [see Article 10(2)]. The product must not contain any substances prohibited by the Regulation (see Articles 14, 15 and Annex II), restricted substances except where they are used in accordance with the restrictions set out in Annex III, certain colorants, certain preservatives, or certain UV-filters. Further details are listed in Article 14.

Before placing the cosmetic product on the market, the responsible person must electronically submit to the Commission certain information, including the presence of substances in the form of nanomaterials [see Article 13(1)(f)]. Electronic submission of information must be done via the Commission's Cosmetic Products Notification Portal (CPNP).

Cosmetic products containing nanomaterials are subject to additional notification requirements. For the purposes of the regulation, nanomaterial means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from (1 to 100) nm.

H.3.3 Nanomaterial ingredients

Cosmetic products containing nanomaterials shall be notified to the Commission by electronic means (via the CPNP) six months prior to being placed on the market, except where they had already been placed on the market by the same responsible person before 11 January 2013. In the latter case, cosmetic products containing nanomaterials had to be notified to the Commission between 11 January 2013 and 11 July 2013.

The regulation states that the information notified to the Commission should contain at least:

a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;

b) the specification of the nanomaterial including size of particles, physical and chemical properties;

c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;

d) the toxicological profile of the nanomaterial;

e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;

f) the reasonably foreseeable exposure conditions.

In the event that the Commission has concerns about the safety of a nanomaterial, it shall request an opinion from the Scientific Committee on Consumer Safety (SCCS) and shall make this information publicly available. Taking into account the SCCS opinion, and where there is a potential risk to human health (including where there is insufficient data), it may amend the lists of prohibited and restricted substances contained in Annexes II and III.

Cosmetic products placed on the market must be properly labelled (see Article 19). The label must include, among other things, a list of ingredients. The Regulation (EC) No 1223/2009 states that all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets.

When a cosmetic product is placed on the market, the responsible person must keep a product information file. The file must be kept for 10 years following the date on which the last batch of the product was placed on the market (see Article 11).

In the event of any serious or undesirable effects, the responsible person and distributors shall without delay notify the Competent Authority of the Member State where the serious/undesirable effects occurred (details contained in Article 23). In the UK, the Competent Authority is defined by the Cosmetic Products Enforcement Regulations 2013 as the Secretary of State for Business, Innovation & Skills (BIS) and the relevant enforcement authority, local authority trading standards departments.

H.4 Detergents

H.4.1 Regulation of detergents

The placing on the market of detergents throughout the EU is governed by the provisions of the European Regulation (EC) No 648/2004 on detergents 2004, as amended by European Commission Regulation (EC) No 551/2009.

The UK has enacted the Detergents Regulations 2010 which deal with fees for applications of derogations from the European Regulation (EC) No 648/2004 on detergents 2004, enforcement of the regulation and penalties for breaches while all other requirements are referred back to the regulations.

The Detergents Regulations 2010 incorporate amendments to the European Regulation (EC) No 648/2004 on detergents 2004 enabled by Commission Regulation (EC) No 551/2009 which relating to an increase in the fees charged for an application for a derogation and enact a ban on the use of inorganic phosphates at certain levels from 1 January 2015.

H.4.2 Obligations on manufactures

Manufacturers of surfactants do not have to request approval of their surfactant or detergent before placing these on the market in the EU, but they must ensure that they only placing on the market surfactants and detergents containing surfactants which meet the requirements of the regulations.

They are responsible for carrying out the relevant biodegradability tests, applying for derogations under the regulations and for breaches of the regulations. Manufacturers are also responsible for holding at the disposal of the competent authority in Member States and medical personnel information on the tests undertaken for approval and derogation, and for providing certain information on their packaging.

Controls include:

a) composition requirements where, before placing on the market surfactants, and detergents containing surfactants, manufacturers must ensure that these substances meet the criteria set out in Annex II of the regulations for ultimate biodegradation;

b) labelling requirements relating to information about products on labels together with data sheets; and

c) information requirements about types or categories of ingredient need to be listed in percentage ranges where they are added in a concentration above 0.2%.

H.4.3 Derogations

The manufacturer of a surfactant which passes the primary biodegradability test but fails the ultimate biodegradability test, and which is to be used for industrial or institutional purposes, can apply for a derogation from the regulations. Derogations are granted by the relevant Member State in accordance with the provisions of the European Regulation (EC) No 648/2004 on detergents 2004.

The UK Detergent Regulations 2010 set out the procedure for each application in accordance with the regulations. It must be submitted by the manufacturer, contain a technical file (including results from the ultimate and primary biodegradability tests as set out in Annexes 2 and 3 of the regulations, and a complimentary risk assessment as set out in Annex 4 of the regulations) and the appropriate fee.

The Commission publishes a list of surfactants which have obtained a derogation with any conditions or limitations of use. The Commission also publishes a list of banned or restricted detergent surfactants, as per Annex VI of the regulations, due to non-compliance with the provisions of the European Regulations (EC) No 648/2004 on detergents 2004.

H.4.4 Other prohibitions or restrictions

A Member State may impose temporary restrictions on a detergent which meets the requirements of the regulation where it has justifiable grounds to believe the detergent constitutes a risk to safety or health of humans or of animals or a risk to the environment. The Member State will immediately notify the Commission and other Member States who shall consult and make a decision within 90 days.

H.5 Electrical equipment

H.5.1 Safety

The Electrical Equipment (Safety Regulations) 1994 implement in the UK the requirements of the EC Low Voltage Directive 2006 (Consolidating Directive 2006/95/EC). It applies to electrical equipment with a voltage between 50 V and 1 000 V for alternating current and between 75 V and 1 500 V for direct current, either for use in homes and the workplace. Some equipment with that voltage is excepted, including:

- equipment for use in an explosive atmosphere;
- equipment for radiology and medical purposes;
- parts for goods lifts and passenger lifts;
- electricity supply meters;
- plugs and socket outlets for domestic use;
- fence controllers;
- specialist electrical equipment for use on ships, aircraft or railways, which conforms to the safety provisions drawn up by international bodies in which the Member States participate; and
- electrical equipment supplied for export to a country who is not in Annex G of the EC Low Voltage Directive 2006.

H.5.2 Requirement of safety

Electrical equipment placed on the market in the EC must be:

a) safe: this means that there should be no risk, apart from one reduced to a minimum, that the electrical equipment will in any way cause death or personal injury to any person including the risk of death or injury to domestic animals and damage to property;

b) constructed in accordance with principles generally accepted within Member States as constituting good engineering practice in relation to safety matters;

c) designed and constructed to ensure that it is safe when connected to the electricity supply system by providing a level of protection against electric shock; and

d) designed and constructed to conform to the Principal Elements of the Safety Objectives. How these objectives are met is up to the manufacturer, or their representative in the EEA, but there is a presumption of conformity where the electrical equipment has been designed and constructed to meet the specifications of a harmonized standard.

H.5.3 Conformance to the safety requirements

The electrical equipment should conform to the following types of standard, listed in order or preference.

a) Harmonized European Standards, which are drawn up by common agreement between the European national standards bodies and notified to the European Commission by the Member States under the Low Voltage Directive 2006. The UK national standards body is the British Standards Institution.

b) International Standards where no relevant harmonized European Standard exists. Electrical equipment which conforms to the specification of a standard published by the International Electrotechnical Commission (IEC) is presumed to comply with the safety provisions of the regulations.

c) National standards where the equipment is constructed to conform to the safety provisions of either a published British Standard or a published standard of the Member State of the manufacturer provided that standard satisfies the safety requirements of the regulations.

In some cases the electrical equipment does not conform to these standards and it is up to the manufacturer or representative to otherwise ensure that the equipment is safe and conform to the safety regulations.

H.5.4 Approval through EC declaration of conformity and CE mark

There is no need for regulatory approval to place electrical equipment on the market in the UK but manufacturers, or their authorized representatives, must issue a written declaration of conformity to the safety regulations. The declaration must:

a) identify the manufacturer or the authorized representative;

b) describe the electrical equipment to which it relates; and

c) where appropriate, specify the harmonized standards or other specifications with which conformity to the safety requirements is declared.

The manufacture or their representative in the EEC or importer into the EEC must keep a copy of this declaration which can be requested by the enforcement authority if it suspects non-compliance with the safety regulations. Not providing the declaration can constitute an offence.

The manufacture bases its declaration on the technical documentation it compiles, which provides the enforcement authorities with the means of assessing the conformity of the electrical equipment to the requirements of the regulations. These documents must describe the electrical equipment to which it relates, contain information about the design, manufacture and operation thereof and set out the procedures used to ensure the conformity of the electrical equipment to the safety requirements.

H.5.5 CE mark

The CE mark is the visible means by which the manufacturer or their authorized representative declares that in their opinion the equipment meets all the requirements of the safety regulations.

Manufacturers, importers and all other suppliers are governed by the CE system as follows.

- A manufacturer who is based within the EEA or their authorized representative may:
  - affix the CE marking;
  - draw up and hold an EC declaration of conformity; and
  - compile and hold the technical documentation.
- Importers are not allowed to affix the CE marking, draw up an EC declaration of conformity or compile the technical documentation. However, if the manufacturer is not established within the EEA and has not appointed an authorized representative the importer will be required to hold:
  - a copy of the EC declaration of conformity; and
  - the technical documentation.
- All other suppliers electrical equipment (e.g. wholesalers, distributors, retailers) in the course of a business have a statutory duty to ensure that the equipment that they are supplying:
  - satisfies the safety requirements; and
  - bears the CE marking.

H.5.6 Safety reports

Notified bodies are specialist bodies appointed by Member States who assess the requirements for compliance with the Safety Directive and assess compliance with these standards. Where the electrical equipment has not been constructed to conform to the specifications of any of the recognized hierarchy of standards, e.g. it is an innovative product, or there is doubt of compliance with the safety regulations, the manufacture or their representatives might want to seek the opinion of the notified body in the form of a safety report before placing on the electrical equipment market.

H.5.7 Importers outside EEA into UK

An importer of electrical equipment importing from countries in the EEA into the UK market is therefore strongly advised to establish the whereabouts of the information or be in a position to obtain the information as soon as possible if an enforcement authority requests to see it.

H.5.8 Enforcement

The regulations are enforced by the local authority trading standards departments in respect of electrical equipment intended for the consumer; and by the Health and Safety Executive (HSE) in respect for equipment intended for the workplace.

There is a presumption that electrical equipment will conform to the safety regulations when it bear the

CE mark. However, enforcement authorities must take action when there are reasonable grounds for suspecting that there is non-compliance.

It is an offence to supply electrical equipment which does not conform to the requirements of the safety regulations. Any person committing an offence is liable, under summary conviction, to imprisonment, a fine or both.

H.6 Fertilizers

H.6.1 General

In order for a fertilizer to be approved for sale or use in the UK it must either be an EC designated fertilizer or conform to UK regulation on fertilizers. A fertilizer that has been approved under UK regulation cannot be sold in the EU unless it is also an EC designated fertilizer or conforms to the local regulation of that Member State.

H.6.2 EC designated fertilizers

For a fertilizer to be able to be placed on the market in the EU it has to conform to The EC Fertilizer Regulation 2003 as amended by Commission Regulation (EU) No 137/2011. The main requirement is for the fertilizer to be designated as an EC fertilizer and this designation will only occur if:

a) the fertilizer is listed in Annex I of the regulation;

b) the manufacturer of the fertilizer is established in the Community; and

c) the fertilizer conforms to all other requirements of the regulations, including packaging and labelling requirements.

In order to obtain the EC fertilizer designation the manufacturer, or their representative, must apply via the competent authority in the Member State in which the manufacturer is established. The application is to be included by the Commission in Annex I of the EC Fertilizer Regulation 2003 (as amended) and submit a technical file containing the fertilizer's characteristics. The Commission assisted by its Working Party on Fertilizers will accept or reject the proposal. This decision is based on the fertilizer providing nutrients in an effective manner, the manufacturer supplying satisfactory relevant sampling, analysis, and if required, test methods, and the fertilizer not adversely affecting human, animal, or plant health, or the environment under normal conditions of use.

There is a Commission guide to the compilation of a technical file on application to designate fertilizers "EC fertilizer", which should be consulted before any application.

H.6.3 Testing conformance to the regulations

Only certain laboratories are authorized to report on conformity of fertilizers to the EC Fertilizer Regulation 2003 (as amended). These need to be approved by Member States and notified to the Commission who then publishes a list of approved laboratories (last updated 24 February 2009).

From 1 January 2007 the bodies that accredit the laboratories must conform to BS EN ISO/IEC 17011, which specifies general requirements for accreditation bodies accrediting conformity assessment bodies. The laboratories themselves must be accredited in accordance with BS EN ISO/IEC 17025 for one or more of the methods listed in the EC Fertilizer Regulation 2003 (as amended) or, up to 18 November 2014 prove that they have initiated and are pursuing this accreditation and have successfully entered inter-laboratory tests with good results.

H.6.4 Enforcement

The enforcement bodies are local authority inspectors appointed for this purpose. They have a number of powers including entering premises, inspecting premises, seizing and destroying fertilizers and taking samples. The Secretary of State or the National Assembly for Wales can issue compliance notices where no offence has been committed but there is a non-compliance with the regulations.

The manufacturer of a fertilizer is responsible for its EC designation and will be guilty of an offence if it places on the market a fertilizer which is not designated as an "EC fertilizer" in accordance with the EC Fertilizer Regulation 2003 (as amended), namely it is not in Annex I and/or where he/she is not established within the Community.

The EC Fertilizer Regulation 2003 (as amended) is implemented by The EC (England and Wales) Fertilizers Regulations 2006, The EC Fertilizers (Scotland) Regulations 2006 and the EC Fertilizers Regulations (Northern Ireland) 2006.

H.6.5 UK fertilizers

Fertilizers for sale only in the UK do not have to be registered as EC Fertilizers but are permitted in the UK if they conform to the 1991 Fertilizer Regulations (SI 1991/2197 as amended). The Fertilizer Regulations 1991 will apply to anyone selling or having in their possession a fertilizer not designated as EC Fertilizers.

H.7 Food

H.7.1 Labelling

The law contains several provisions on the labelling of foodstuffs. The General Food Regulation (EC) No 178/2002, which lays down general principles and requirements of food law in all Member States including the UK, states that foodstuffs must be adequately labelled. It requires, among other things, that the labelling and presentation of foodstuffs does not mislead consumers (Article 16).

In the UK, further food labelling requirements can be found in the Food Labelling Regulations 1996. According to these regulations (see Part II for full details), foods must be labelled with specific information, such as:

- the name of the food;
- a list of ingredients, in descending order by weight [and in accordance with the Weights and Measures Act 1985 and the Weights and Measures (Packaged Goods) Regulations 2006];
- the appropriate durability indication (i.e. "use by");
- any special storage conditions or conditions of use;
- the name and address of the manufacturer or packer, or a seller established within the European Community; and
- instructions for use.

Currently, regulation does not require that labels include details of the particle size of ingredients. Although such details can be included voluntarily, this is set to change. The requirements on labelling are now largely consolidated in European Regulation (EU) No 1169/2011 on the provision of food information to consumers, which will be brought into effect for most purposes by 2014 (and by 2016 for nutrition labelling). Note in particular, once in force, Article 19 (4) of this regulation will require that all ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients should be followed by the word "nano" in brackets.

European Regulation (EU) No 1169/2011 begins to take effect in 2014 and a draft Food Information (England) Regulations 2013 is considering matters of enforcement.

Labels must appear either on the packaging, on a label attached to the packaging, or on a label that is clearly visible through the packaging. Furthermore, they must be easy to see and understand, clearly legible and indelible.

As well as the general labelling requirements, certain foods are subject to additional requirements set out in other, food-specific regulation. For instance, cocoa or chocolate products must also conform to labelling provisions of the Cocoa and Chocolate Products (England) Regulations 2003. These types of regulation for specific foodstuffs are not covered in the PAS but examples of foods covered by food-specific regulation are given in regulation 4(2) of the Food Labelling Regulations 1996 which exempts certain foods, specifically governed by other regulations from Part II of the 1996 regulations.

Another example relates to genetically modified organisms (GMOs). The intentional presence of GMOs in food must be labelled. This requirement does not apply, however, where the presence of GMOs is adventitious or technically unavoidable and constitutes no more than 0.9% of the food ingredients.

GMO labelling requirements are set out in Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed and Regulation (EC) No 1830/2003 Concerning Traceability and Labelling.

The European regulations for food information to consumers aims to make food labelling easier for the consumer to understand. It consolidated labelling requirements on issues such as country of origin and allergens and it introduces nutrition labelling.

For further information on the legislative requirements, see the Food Standard Agency's *Clear Food Labelling Guidance*, which is available from: http://www.food.gov.uk/multimedia/pdfs/clearfoodlabelling.pdf.

H.7.2 Novel foods

H.7.2.1 General

The Novel Foods and Novel Food Ingredients Regulations 1997 sets out detailed rules relating to novel foods. It operates in conjunction with the General Food Law Regulations 2004 which states that foods and food ingredients must not:

- present a danger to the consumer;
- mislead the consumer; or
- be nutritionally disadvantageous to the consumer.

H.7.2.2 Definition of novel foods

Novel foods or food ingredients are those which were not generally available for human consumption in the EU prior to 15 May 1997 and:

- contain, consist of, or were produced from GMOs;
- have a new or intentionally modified primary molecular structure;

- consist of or are isolated from micro-organisms, fungi or algae;
- consist of or are isolated from plants, or constitute food ingredients isolated from animals (except for food and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use); or
- have been subject to a production process not currently used, giving rise to significant changes in their composition or structure which affects their nutritional value, metabolism or level of undesirable substances.

This definition does not include food additives, flavourings, and extraction solvents used in the production of food which are covered by separate EU legislative provisions. For regulation on food additives (e.g. sweeteners, colours, miscellaneous other additives) see Commission Regulation (EU) No 231/2012.

H.7.2.3 Restrictions on marketing of novel foods

Novel foods and food ingredients cannot be placed on the market unless they fulfil a host of requirements, including the requirement that they are labelled with certain information (se Article 8) such as:

- any characteristic or property which renders it no longer equivalent to an existing food or food ingredient;
- the presence of material not present in an existing equivalent foodstuff and which might have implications for the health of certain sectors of the population, or which raises ethical concerns; and
- the presence of GMOs.

Where, for example, the inclusion of nanomaterials and nanotechnology-based products alters the characteristics or properties of a food so that it is no longer equivalent to an existing product, the label must indicate its new characteristics or properties. However, there is no requirement that labels include details of the particle size of ingredients.

Novel foods cannot be placed on the market unless they have been authorized. Manufacturers and suppliers wishing to market a novel food or food ingredient must submit an application to the Competent Authority of the Member State in which the product will be placed for the first time. In the UK, the Competent Authority is the Food Standards Agency (FSA). Manufacturers and suppliers must also ensure they send a copy of the application to the European Commission. Commission Recommendation 97/618/EC sets out what to include in the application, such as information on the composition, nutritional value, production process, toxicology and safety of the novel food in question.

Once the application has been received, the FSA has 90 days to produce an initial opinion based on a pre-market safety assessment carried out by the Advisory Committee on Novel Foods and Processes (ACNFP). The initial opinion will then be circulated to all EU Member States who are invited to comment. If Member States do not raise objections, the novel food will be authorized or rejected, depending on the FSA's initial opinion.

If an objection is raised, or the FSA requests that additional safety assessments are conducted, a decision will be taken by the Standing Committee for the Food Chain and Animal Health (SCFCAH). If necessary, the SCFCAH will ask the European Food Safety Authority for its opinion on any outstanding safety issues. Should the SCFCAH fail to come to a decision by qualified majority, the matter will be transferred to the Council of Ministers.

H.7.2.4 Substantial equivalence

Not all novel foods or food ingredients have to undergo this application and assessment process. Novel foods or food ingredients that are "substantially equivalent" to existing food or food components are subject to a simplified procedure. This procedure involves submitting a notification to the European Commission after an opinion on equivalence has been obtained by the FSA. Before it can issue its opinion, the FSA requires the manufacturer or supplier to submit a dossier in which the food or ingredient in question is shown to be substantially equivalent to a food or ingredient already on the EU market as regards its:

- composition;
- nutritional value;
- metabolism;
- intended use; and
- level of undesirable substances.

Guidance on what is required to demonstrate substantial equivalence is given in ACNFP guidelines for the presentation of data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart. The guidelines are available from: http://www.food.gov.uk/multimedia/pdfs/seguidelines.pdf

Proposals for a new novel foods regulation are currently being considered by EU institutions. If adopted, the definition of "novel food" will explicitly cover "food containing or consisting of engineered nanomaterials not used for food production within the Community before 15 May 1997".

H.7.2.5 Additives, supplements, flavourings and enzymes

Persons wishing to place food additives on the EU market should check that it is listed (as permitted subject to conditions) by Annexes II/III of European Regulation (EC) No 1333/2008. The specification of the additive is controlled by Regulation (EU) No 231/2012.

Manufacturers of food supplements should check the lists contained within Schedules 1 and 2 of Directive 202/46/EC. Where the supplement is not listed, it will need to be evaluated by the European Food Safety Authority.

Persons wishing to place food flavourings on the EU market should follow a similar process, checking whether the flavouring is authorized under Regulation (EC) No 1334/2008 and applying to have the list updated if necessary.

Persons wishing to place food enzymes on the EU market should check that they are authorized under Regulation (EC) No 1332/2008. Where this is not the case, manufacturers should apply to have the list of permitted flavourings updated. It is important that food enzymes are labelled in accordance with the regulation.

H.8 Medicinal products

H.8.1 Licences

The UK law on the authorization and marketing of human medicines is largely consolidated in the Human Medicines Regulations 2012. A medicinal product cannot be placed on the market in the UK unless certain licences have been obtained from the Medicines and Healthcare Products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). Examples of licences include the following:

- Marketing authorization
  - The product itself must have a marketing authorization. The type of application required will depend on the nature of the product's active ingredient. The format of applications will vary between, for instance, new active substances and biological and biotechnology products.
  - Applications must be accompanied by a common technical dossier. Data requirements are set out in Notice to Applicants published by the European Commission's Committee for Medicinal Products for Human Use (CHMP). Data requirements depend on whether new active substance.
- Parallel import licence
  - A parallel import licence must be obtained to allow medicinal products authorized in other EU Member States to be sold in the UK (provided there is no therapeutic difference between the imported products and the product on which an application is based). Further guidance on the submission of applications for parallel import licences is given on the MHRA website.
- Manufacturer's and wholesale dealer's licences
  - Under the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, a licence must also be obtained by the companies involved in the manufacture and distribution of the product. Application forms and guidance notes can be accessed via the MHRA website on manufacturer's and wholesale dealer's licences.

H.8.2 Definition of medicinal product

Sometimes it can be difficult to distinguish between a medicinal product and other products such as cosmetics and foods subject to separate legislative requirements. The MHRA Guide to What is a Medicinal Product explains how "medicinal product" is defined and clarifies the status of borderline products.

Further information can be obtained from the MHRA Regulatory Information Service (see Table 6).

H.8.3 Clinical trials

As outlined in **H.8.1**, medicinal products need to have a marketing authorization granted before they can be sold or supplied to patients. Before this authorization is granted, information about the product is assessed to ensure that it is safe and effective and also that the quality of the product is sufficient.

Clinical trials are undertaken to allow data on the safety and efficacy of new products to be collected. These trials can be conducted using healthy volunteers or patients, depending on the type of product and its stage of development. Information on the non-clinical safety must be obtained before the clinical trial programme commences; see further:

- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;
- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.

H.9 Pesticides

H.9.1 General

The regulation of pesticides includes the control of the use of agricultural pesticides (including horticultural and home garden pesticides) and non-agricultural pesticides (public hygiene pesticides). The main laws which regulate the use, supply, storage and advertisement of pesticides in GB are the Control of Pesticides Regulations 1986 (as amended 1997) (COPR), the Plant Protection Products Regulations 2011 (PPPR) which allows enforcement of the European Plant Protection Products Regulation No 1107/2009 and the Control of Substances Hazardous to Health Regulations 2002 (see **H.9.2**).

H.9.2 Approvals

Before a pesticide can be advertised, sold, supplied, stored or used in GB it has to be approved under the Control of Pesticides Regulations 1986 (COPR) (as amended in 1997). This means that not only manufacturers and distributors have obligations under COPR but also all users and even advertisers of these products.

Approval is granted by Ministers following an application from a manufacturer, formulator, importer or distributor (or in certain circumstances a user) supported by the necessary information. Approvals are subject to specific conditions or to general conditions and they are normally granted for individual products and for specific uses. They are always open to immediate revocation, suspension or amendment at any time depending on safety considerations.

H.9.3 Offences

It is an offence to advertise, sell, supply store or use non-approved pesticides or use an approved pesticide without complying with any conditions that might attach to the approval. The enforcing authorities are the HSE and local authority inspectors, trade inspectors (with responsibility for advertisement and the retail sale of pesticides), and the devolved administrations of the UK.

H.10 Plant protection products

Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides, is transposed in the UK by the Plant Protection Products (Sustainable Use) Regulations 2012. The Directive demands that Member States adopt National Action Plans to reduce risk to human health and the environment posed by pesticide use. National Action Plans should have been submitted to the European Commission by 14 December 2012.

In addition to the regulation under REACH, there are specific national regulations in the UK which apply to research and development uses of biocides and agricultural, home garden and horticultural pesticides. For pesticides, the relevant regulation is Control of Pesticides Regulations 1986 (COPR) and Plant Protection Products Regulations 2011 (PPPR).

Research and development with pesticides might require a permit for trial purposes from the Chemicals Regulation Directorate of the HSE. It should be assumed that this is required unless the work falls under one of the following exemptions.

a) Research material, including the experimental pesticide, is not released into the environment (e.g. all work is done in laboratories or glasshouses), and all materials are appropriately destroyed.
b) All research and development work will be carried out within the conditions of use of a currently approved pesticide.
c) The research and development is an extrapolation of previous work.

Farmer demonstration trials of pesticides cannot be carried out under a permit for trial purposes and if these are to be conducted, the Chemicals Regulation Directorate should be contacted directly.

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