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| **ALIGNMENT OF NINE EU SINGLE MARKET DIRECTIVES WITH THE NEW LEGISLATIVE FRAMEWORK** |
| Consultation on UK implementation |
| AUGUST 2015 |

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# Alignment of nine EU Single Market Directives with the New Legislative Framework: Consultation on UK implementation

In 2006 the European Commission conducted a review into the functioning of the internal market for goods. It concluded that the EU harmonised legislation was not as effective as it should be. By way of response the New Legislative Framework (“NLF”) was created. In order to bring existing product harmonisation legislation into line with the Decision, there has been a process at the EU level to align a number of Directives with the NLF.

A number of these recast Directives were agreed in April 2014, and must be transposed into national law by April 2016. This consultation seeks your views on the implementation of these Directives in the UK.

This consultation is being taken forward jointly with the Health and Safety Executive (HSE), which is the policy lead for the Civil Explosives Directive (one of the Directives covered by the NLF, and included in the consultation exercise).

Issued: 4th August 2015

Respond by: 29th September 2015

Enquiries to:

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This consultation is relevant to: (a) manufacturers, importers and distributors; (b) bodies involved in conformity assessment (c) enforcement authorities; (d) end-users (including consumers)

## 1. Executive Summary

1. In 2006 the European Commission conducted a review into the functioning of the internal market for goods. It concluded that the EU harmonised legislation was not as effective as it should be. In particular, three main deficiencies were highlighted:

* The high number of products that were on the EU market that did not comply with product safety legislation;
* The unsatisfactory performance of some conformity assessment bodies; and
* The difficulties that many stakeholders faced in understanding and using the EU legislation.

1. By way of response the New Legislative Framework ("NLF") was created. The core principles of the NLF are that:

* Legislation governing products should be clear and more consistent across sectors;
* The obligations of all economic operators in the supply chain should be set out in more detail;
* Provision should be made to ensure that products are more traceable
* Those bodies which carry out conformity assessments should have certain attributes (e.g. independence and capability) and certain operational obligations; and
* Each Member State should have robust, but proportionate, market surveillance and enforcement mechanisms in place based on a set of common requirements at the EU level.

1. In order to bring existing product harmonisation legislation into line with the Decision, an "Alignment Package" was introduced to align nine European Union Directives (which would not otherwise have been revised in the near future) to the NLF. The Alignment Package was fully published in March 2014. Other EU product legislation will also be aligned to the NLF when it undergoes a formal review.
2. In addition, the Pressure Equipment Directive (97/23/EC) was aligned with the NLF and Regulation 1272/2008/EC on the Classification, Labelling and Packaging of Substances and Mixtures (CLP). The revised Directive was published in June 2014.
3. The table below shows which Directives and industries are affected by the Alignment Package:

|  |  |  |
| --- | --- | --- |
| **Name** | **“Old” Number** | **“New” Number** |
| Low Voltage | 2006/95 EC | 2014/35 EU |
| Simple Pressure Vessels | 2009/105 EC | 2014/29 EU |
| Lifts and their safety components | 1995/16 EC | 2014/33 EU |
| Equipment for use in Potentially Explosive Atmospheres (ATEX) | 94/9EC | 2014/34 EU |
| Electromagnetic Compatibility | 2004/108 EC | 2014/30 EU |
| Measuring Instruments | 2004/22 EC | 2014/32 EU |
| Non Automatic Weighing Instruments | 2009/23 EC | 2014/31 EC |
| Civil Explosives | 93/15 EC | 2014/28 EU |
| Pressure Equipment | 97/23/EC | 2014/68/EU |

1. The Directive on Pressure Equipment (Directive 2014/68/EU) is being implemented in two stages. The first stage, alignment with Regulation 1272/2008/EC on the Classification, Labelling and Packaging of Substances and Mixtures (CLP), was completed in February 2015 and was the subject of a previous consultation. It is not covered by this exercise. The second stage, alignment with the NLF, is due to be completed by July 2016 and is included in this consultation.
2. The UK has an obligation under EU law to implement the Directives and in doing so we must ensure that we secure the objectives of the Directive. However we have a degree of choice as to how we do that.
3. The Directives impose new obligations on manufacturers, importers and distributors. They also make detailed provisions concerning the bodies which are entitled to carry out conformity assessments and the market surveillance regime.
4. We propose to implement the Directives by making the 2016 Regulations and in the case of Civil Explosives by amending the Explosive Regulations 2014. In order to help us understand the likely impacts we are seeking responses to the questions set out in Section 4.
5. We will make Regulations to implement the NLF Directives. Drafts of this legislation can be found in Annex 1. These Regulations will revoke and replace the following legislation:

|  |  |  |
| --- | --- | --- |
| **Existing Directive** | **Existing Legislation** | **New Directive** |
| 2006/95 EC | Electrical Equipment (Safety) Regulations 1994 | Low Voltage 2014/35 EU |
| 2009/105 EC | The Simple Pressure Vessels (Safety) Regulations 1991 | Simple Pressure Vessels 2014/29 EU |
| 1995/16 EC | The Lifts Regulations 1997 | Lifts and their safety components 2014/33 EU |
| 94/9EC | The Equipment and Protective Systems Intended for Use in Explosive Atmospheres Regulations 1996 | Equipment for use in Potentially Explosive Atmospheres (ATEX) 2014/34 EU |
| 2004/108 EC | Electromagnetic Compatibility Regulations 2006 | Electromagnetic Compatibility 2014/30 EU |
| 2004/22 EC | The Measuring Instruments Regulations 2006  *(there are 15 individual instrument regulations plus amendment regulations which will be revoked and replaced by one omnibus regulation covering all instrument types).* | Measuring Instruments 2014/32 EU |
| 2009/23 EC | Non-automatic Weighing Instruments Regulations 2000 | Non Automatic Weighing Instruments 2014/31 EU |
| 93/15 EC | The Explosives Regulations 2014 | Civil Explosives 2014/28 EU |
| 97/23/EC | Pressure Equipment Regulations 1999 | Pressure Equipment 2014/68/EU |

1. As the Directives have already been made we can no longer influence their content. However we are keen to have the views of stakeholders on our approach to implementation of those Directives. We have set out a number of specific questions on which we are asking for responses. In addition we are seeking further information on the likely impacts of these Regulations to ensure our Impact Assessment correctly reflects the likely costs and benefits.
2. This consultation will be relevant to:

* Manufacturers, importers and distributors
* Bodies involved in conformity assessment
* Enforcement authorities
* End-users (including consumers)

1. This consultation is being taken forward jointly with the Health and Safety Executive (HSE), which is the policy lead for the Civil Explosives Directive (one of the Directives covered by the NLF, and included in the consultation exercise). HSE will also work with an explosives stakeholder group, during the consultation period, to discuss the revisions in the context of their industry. The explosives industry will be invited to formally respond to the joint BIS/HSE consultation and HSE will consider the consultation responses jointly with BIS. The Minister of Justice, Northern Ireland, will in due course consult on equivalent changes to The Placing on the Market and Supervision of Transfers of Explosives (Northern Ireland) Regulations 1993.

## 2. How to respond

1. When responding please state whether you are responding as an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents by selecting the appropriate interest group on the consultation form and, where applicable, how the views of members were assembled. Please also tell us which specific Directives you have an interest in, if applicable.
2. The consultation response form is available electronically on the consultation page: <https://www.gov.uk/government/consultations/XXX> (until the consultation closes). The form can be submitted by email or by letter to:

|  |  |
| --- | --- |
| **BIS** |  |
| Victoria Griffiths |  |

1 Victoria Street

London

SW1H 0ET

T: 0207 215 6212

E: [nlfalignmentconsultation@bis.gsi.gov.uk](mailto:nlfalignmentconsultation@bis.gsi.gov.uk)

1. A list of those organisations and individuals consulted is in Annex B. We would welcome suggestions of others who may wish to be involved in this consultation process. Please feel free to forward this consultation to anyone you think may be interested.
2. You may make printed copies of this document without seeking permission.

## 3. Confidentiality & Data Protection

1. Information provided in response to this consultation, including personal information, may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want information, including personal data that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.
2. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

## 4. Help with queries

1. Questions about the policy issues raised in the document can be addressed to:

Victoria Griffiths

Department for Business, Innovation and Skills

Single Market Product Regulation

European Reform Directorate

4th Floor Spur 1

1 Victoria Street

London SW1H 0ET

Tel: 020 7215 6212

Email: nlfalignmentconsultation@bis.gsi.gov.uk

Questions about the policy issues raised in the document as they relate to civil explosives can be addressed to:

Explosives Policy Team

Health and Safety Executive

Building 5S2

Redgrave Court

Merton Road

Bootle

L20 7HS

Tel: 0151 951 3356

Email: explosives.policy@hse.gsi.gov.uk

The consultation principles are in Annex A.

## 5. The proposals

1. The NLF Directives revoke and replace the Directives set out above in section 1.3. Although this will mean some changes in UK law, many things will remain the same. This part of the consultation document highlights the key respects in which the law will change or, where the provisions below already exist, be reaffirmed.

### Obligations of manufacturers

1. Manufacturers will need to provide instructions and safety information with a product in a language which is easily understood by consumers and end-users
2. They will also need to ensure that products bear the CE marking (which demonstrates conformity with the essential requirements of the Directive) and that they are accompanied by the required documents
3. Manufacturers will also need to ensure that the name and address of the manufacturer is indicated on the product or its packaging
4. They should also carry out sample testing on products which they have supplied, when this is appropriate in the light of the risks presented by a product to the health and safety of consumers. If necessary, they must also keep a register of complaints, non-conforming products and product recalls and keep distributors informed about such monitoring

*(this requirement does not apply to the Directive on Explosives for Civil Use)*

### Obligations of Importers

1. Importers will need to keep a copy of the EU declaration of conformity and ensure that the technical documentation can be obtained when it is requested by authorities
2. They will be obliged to check that the manufacturer outside the EU has applied the correct conformity assessment procedure
3. In addition, they should check that products bear the CE marking and are accompanied by the required documents
4. Furthermore importers should ensure that the name and address of both the manufacturer and importer is indicated on the products or the packaging
5. They should also carry out sample testing and product monitoring as it applies to manufacturers

*(this requirement does not apply to the Directive on Explosives for Civil Use)*

### Obligations of all Economic Operators (EOs): Manufacturers, Importers, Distributors, Lift Installers

1. Introduction of traceability requirements: ensure traceability of products throughout the whole distribution chain. Manufacturers and importers must put their contact details on the product or, where this is not possible, on the packaging or an accompanying document.
2. Furthermore every economic operator must be able to inform the authorities of the economic operator from whom he purchased a product and to whom he supplied it.
3. Reorganisation/streamlining of safeguard clause procedure (i.e. the procedure followed when a product is non-compliant and poses a risk): the new procedure ensures that the relevant enforcement authorities are informed about products which pose a risk and that similar action is taken against that product in all Member States

### Measures intended to ensure the quality of the work performed by Notified Bodies (NBs)

1. Reinforcement of the notification requirements for NBs: To be authorised to carry out conformity assessment activities under the Directives, NBs must satisfy certain requirements. All NBs must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place for risk-based assessments which take due account of the size of the enterprise and the degree of the complexity of the product assessed. Subcontractors and subsidiaries, which carry out parts of the conformity assessment, must also fulfil the notification criteria.
2. Revised notification process: Member States notifying an organisation as a NB must include information on the valuation of competence of that body. Other Member States may object to the notification within a certain period. Where competence is demonstrated by an accreditation certificate, a facilitated procedure applies. Where Member States have not used accreditation to evaluate the body's competence, documentary evidence must be provided and the objection period is longer (at 2 months).
3. Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of NBs): Specific requirements and obligations for notifying authorities are introduced according to which they must be organised and operated so as to safeguard objectivity, impartiality and competence in carrying out their activity. Notifying authorities must de-notify bodies which no longer meet the notification requirements or fail to fulfil their obligations
4. Information and other obligations for NBs: NBs must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other NBs about negative conformity assessment results. They must perform conformity assessment in a proportionate manner taking due account of the size of an enterprise, the structure of a sector, the complexity of the product technology etc.

### Measures intended to ensure more consistency between the Directives

1. Alignment of commonly used definitions and terminology: Definitions of common terms like "manufacturer", "importer", "placing on the market" are introduced into the Directive concerned. Existing conflicting definitions are removed.
2. Alignment of the texts and certain elements of the conformity assessment procedures: The existing text of the modules in the Directives is aligned with the standard modules set out in Annex II to the NLF Decision.

## 6. Consultation questions

1. The consultation questions are listed below. We are asking the questions to get a better idea of the impact on people and organisations affected by the changes in legislation, which will in turn inform the impact assessment.

### Questions asking you for your general views on the changes

**Question 1** - Do you expect any benefits from the proposed changes? If so, what would they be; what evidence do you have for them; and how great would they be?

**Question 2** - Can you think of any possible unintended consequences as a result of these changes? If so, what are they?

**Question 3** - Are there any areas covered by the new Directives on which it would be beneficial to have more guidance for consumers, importers and/or manufacturers? If so, please give details.

**Question 4** – (a) Do you consider that the draft regulations (either individually or collectively) are effective and proportionate? If not, please explain why you think this is the case. (b) Do the draft regulations impose requirements which go beyond the requirements set out in the new Directives and which you consider to be disproportionate or unnecessary? If so, please explain why you think this is the case.

### More specific questions about the requirements of the regulations and how they should be implemented, including on specific regulations

**Question 5 -** Should the template for the declaration of conformity be added as a Schedule to the regulations or should this cross-reference to the Annex to the Directive? Why?

**Question 6 -** Should the Regulations cross-refer to the Annexes in the Directives or should the text of the Annexes be included (where possible) in Schedules to the Regulations? Why?

**Question 7 -** The Directives require that instructions and safety information must accompany the product in a language which can be easily understood by consumers and end-users, as determined by the Member State concerned. Should the Regulations specify that for products made available to end-users in the United Kingdom, English is the language which can be easily understood to ensure greater clarity? Or would this be too restrictive?

**Question 8 -** Should the new Regulations covering the different product strands all follow the same structure? Why?

**Question 9** - Should provisions which are common to each of the Directives be implemented in exactly the same way (where possible) - e.g. using exactly the same language - in the various sets of regulations?

**Question 10** - Do you agree with the Non Automatic Weighing Instruments (NAWI) and Measuring Instruments Directive (MID) draft regulations (where applicable) including the in-service control of individual measuring instruments on the UK market place? Please note that the provisions complement the safeguard clause of the Directives and are identical to those already in existence in the current legislation.

**Question 11** - Do you agree with the proposal to align the requirements for gas and electricity meters with those of the other MID instruments, thereby allowing meters approved under national legislation to be put into use after 30th October 2016? This will allow meters held in stock by suppliers or asset owners to continue to be put into use after this date; thereby avoiding the need for suppliers and asset owners to dispose of these assets.

**Question 12** - Can you provide an estimate of the cost saving by allowing these meters to continue to be put into use after 30th October 2016? If so, what is this based on?

**Question 13** - Do you agree with the LVD draft regulations specifying the requirement for a safe connection to BS1363 style socket outlets and revoking the equivalent requirement in the Plugs and Sockets, etc (Safety) Regulations 1994 (SI 1994:1768)? Why?

### Questions about the estimates of figures/costs we have used/are seeking more information about

1. When answering the questions in this section, please make clear which IA / sector you are referring to

**Question 14** - Do the Impact Assessments adequately reflect the effect of the new Directives?

**Question 15** - Do you agree with our estimate of the number of businesses affected in each sector? Can you provide additional evidence?

**Question 16** - Are you able to provide any evidence (quantified or otherwise) of the likely costs of the changes for the main affected groups i.e. manufacturers, importers or distributors? If so, what is this based on?

**Question 17** - Do you agree with our estimate of the average costs (one-off and on-going) to business? Can you provide additional evidence to support your answer? If so, what is this based on?

**Question 18** - Do you agree with our estimate of the average costs to Notified Bodies? Can you provide additional evidence to support your answer?

**Question 19** - What is your estimate of the costs on a yearly basis for your business in complying with the Regulations, in terms of either additional time spent in complying with the regulations or financial costs? Please specify whether the costs have been calculated using additional time spent or financial costs. If using additional time spent please provide an estimate of the additional number of hours required alongside costs?

1. Question 20 refers to all directives covered in the BIS Impact Assessment (i.e. all except for the Civil Uses Explosives Directive).

**Question 20** - If you are able to be more specific, can you give an estimate of the costs to business for (i) Familiarising themselves with the legislation; (ii) Holding the additional data; (iii) Obtaining new conformity assessment documentation; (iv) Post-marketing obligations?

1. Question 21 refers to the Civil Uses Explosives Directive only.

**Question 21** (a) Do you agree with the assumptions made when estimating costs to manufacturers of the following? If not, why not? Could you provide alternative estimates? What are these based on:

* Familiarisation;
* conformity attestation;
* packaging;
* procedures when products pose a risk.

(b) Do you agree with the assumptions made when estimating costs to distributors and importers of the following? If not, why not? Could you provide alternative estimates? What are these based on?

* Familiarisation
* checking packaging and safety requirements
* taking action following receipt of non-compliant products

(c) Could you provide additional estimates of costs to manufacturers for translation of safety information? If so, what have you based these on?

(d) Could you provide additional estimates of costs to importers for annotating the explosives with their details? If so, what have you based these on?

### Questions about penalties

**Question 22** - In order to implement the NLF Directives we must set effective, proportionate and dissuasive penalties for infringements. Should the new legislation have a consistent approach to penalties across all the implementing regulations?

### Questions about redress

**Question 23** - Is the level of redress in the new legislation sufficient? Why?

### General question

**Question 24** - Do you have any other comments that might aid the consultation as a whole?

## 7. What happens next?

1. This consultation is necessary to enable the United Kingdom to make the new legislation required to implement the requirements of the Directives. A response to this consultation will be made and following the date of this issue the Regulations will be laid in Parliament to come into force on 20th April 2016 (19th July 2016 for the Pressure Equipment Directive). The Government’s Response Document will be placed on the BIS website, with paper copies of the summary made available on request.

## Annex A: Consultation principles

The principles that Government departments and other public bodies should adopt for engaging stakeholders when developing policy and legislation are set out in the consultation principles.

<http://www.cabinetoffice.gov.uk/sites/default/files/resources/Consultation-Principles.pdf>

### 

### Comments or complaints on the conduct of this consultation

If you wish to comment on the conduct of this consultation or make a complaint about the way this consultation has been conducted, please write to:

Angela Rabess

BIS Consultation Co-ordinator,

1 Victoria Street,

London

SW1H 0ET

Telephone Angela on 020 7215 1661

or e-mail to: [angela.rabess@bis.gsi.gov.uk](mailto:angela.rabess@bis.gsi.gov.uk)

If you wish to comment on the conduct of this consultation or make a complaint about the way this consultation has been conducted by HSE, please write to:

Jason Cole

HSE Consultation Co-ordinator

7th Floor, Caxton House

6-12 Tothill Street

London

SW1H 9NA

Email: [Jason.cole@hse.gsi.gov.uk](mailto:Jason.cole@hse.gsi.gov.uk)

However if you wish to comment on the specific policy proposals you should contact the relevant policy lead (see section 6).

## Annex B: List of Individuals/Organisations consulted

|  |  |  |
| --- | --- | --- |
| ABCB | DNV Certification Ltd | MICA Associates |
| ABS Group | Dr Clifton Martin | Mike Tebbutt |
| ACPO FELWG | EAICEM | MIRA |
| Agricultural Engineers Association | Economic Development Office | MOD |
| AJA Registrars Ltd | Edward Haynes | Moody International Ltd |
| AJV Regulatory Services | EIEMA | Mr J C Pyle |
| Allcord Ltd | Electrical Contractor's Association | Ms Caroline Warne |
| Allied Approvals Limited | Electrical Safety Council | Ms Kerry Somerset |
| Approved Cables Initiative | Elfab Ltd | National Association of Goldsmiths |
| Arrowhead Industrial Services Limited | EMC Test Laboratories Association | National Measurement Office |
| ASCB(E) | EMEA | National Physical Laboratory |
| Association of British Certification Bodies | Engineering and Machinery Alliance | National Security Inspectorate |
| Association of British Healthcare Industries | Engineering Equipment and Material Users Association | Nemko Ltd |
| Association of Manufacturers of Domestic Appliances (AMDEA) | Environment Agency | Nigel Cadwallader |
| AstraZeneca UK Ltd | EPC-Europe | Norman Greig |
| Astrium Products | EQUITOY | NSF-CMi Certification Ltd |
| AV Technology Ltd | Expert Ease International | Nuclear Electric |
| Barry Cartman | Explosives Developments Limited | Occupational Safety and Health Editorial |
| BM Polyco Ltd | Event Horizon | OFCOM |
| Bolle Safety | FBE Management Ltd | Office for Nuclear Regulation |
| Boots UK Limited | Federation of Small Businesses | Orica |
| BPMA | FETA | ORR |
| BRE | Fire Brigades Union | Pall Corporation |
| British Approvals Board of Telecommunications | Foodstandards Agency | Panasonic UK |
| British Approvals Service for Cables | Forecourt Equipment Federation | Pera |
| British Association of Leisure Parks, Piers & Attractions | Gambica | Peter Morris |
| British Board of Agrément | GeoLang Ltd | Pharmaceutical & Medical Device Technology Consultants |
| British Cables Association | GL Noble Denton | Portable Electric Tool Manufacturers Association |
| British Chambers of Commerce | Graham Hart (Process Technology) Ltd | Qualidoc |
| British Compressed Air Society | Greenham | QinetiQ |
| British Electrotechnical and Allied Manufacturers Association | Halfords | Risk Management Services |
| British Fluid Power Association | Haliburton | Ramora UK |
| British in Vitro Diagnostics Association | Hartley Jones Innovation Ltd | Road Haulage Association Ltd |
| British Industrial Truck Association | Health and Safety Executive (HSE) | Rotating Electrical Machines Association (REMA) |
| British Inspecting Engineers Ltd | Health Protection Agency | RWE Npower Plc |
| British Retail Consortium | Hewlett-Packard | Safety Assessment Federation |
| British Safety Council | HMRC | SATRA Technology |
| British Safety Industry Federation | Home Office | SBAC |
| British Toy and Hobby Association | Ian Andrews | SBGI |
| British Water | Ian Roberts | Security Systems and Alarms |
| Bruel & Kjaer UK Ltd | ICMA | SGS UK Ltd |
| BSI Management Systems Poland | IFIA | SIRA |
| BSI Management Systems UK | IIOC | Skew Energetics |
| BSI Product Services | INSPEC International Ltd | Small Electrical Appliance Marketing Association |
| Bureau Veritas Quality International Ltd | Institute of Explosives Engineers | SMI |
| Bureau Veritas UK Limited | Institute of Occupational Medicine | SMMT |
| Campden & Chorleywood Food Research Association Group | Intellect | Society of British Water Industries |
| Cardiff Trading Standards | International Federation of Inspection Agencies (IFIA) | Society of Martime Industries |
| Cast Metals Federation | International Lift & Escalator Consultants | Spirax Sacro Ltd |
| Catering Equipment Suppliers Association | International Powered Access Federation | Stephen Phillips |
| CBI | International Register Certified Auditors | Suffolk Trading Standards |
| CBI – Explosives Industry Group | International Society for Quality in Health Care | Technology International (Europe) Ltd |
| CEHOG Consumer Protection Sub-Group | Intertek Labtest UK Limited | Trades Union Congress |
| CERAM | Invest Northern Ireland | Trading Standards Institute |
| Certification International (UK) Ltd | ISOQAR | TUV Product Services |
| Chartered Institution of Building Services Engineers | Jamie Collard | TUV SUD Product Service |
| Chartered Quality Institute | Jerry Harrington | TUV UK Ltd |
| Chemical Industries Association | John Liscombe Ltd | TWI Certification Ltd |
| Chemring | Joint Accreditation System of Australia and New Zealand | UK Cares |
| CHKS | Kellogg Brown & Root Limited | UK Cleaning Products Industry Association |
| CIPS | Lighting Association Ltd | UKAS |
| Civil Aviation Authority | Lighting Industry Federation | UL International (UK) Ltd |
| Coherent Tech Ltd | Lloyd’s Register Quality Assurance | University of Portsmouth |
| Conformance Ltd | Lloyd's Register Verification Limited | VCA |
| Construction Equipment Association | Local Better Regulation Office | VCA Dangerous Goods Office |
| Cosmetic Toiletry and Perfumery Association | LRQA Centre | VOSA |
| David Burdett | Lubrizol Limited | Wallop Defence Systems Ltd |
| Department for Environment, Food and Rural Affairs | Manufacturing Technologies Association | WEB Processing (M/C) Ltd |
| Department for Communities and Local Government | Martin Baker | Which? |
| Department for Energy and Climate Change | MCA | Wood Panel Industries Federation |
| Department for Transport | MCGA | Worldwide Quality Assurance Limited |
| Department of Enterprise, Trade & Investment Northern Ireland | Metra Martech |  |
| Department of Health | MHRA |  |
| Department of Health (MHRA) | Michael Clarke |  |
| Department of Justice, Northern Ireland |  |  |
| Det Norske Veritas BV (DNV) |  |  |

## Annex C: Alignment of nine EU Single Market Directives with the New Legislative Framework: Consultation on UK implementation – Response Form

The Department may, in accordance with the Code of Practice on Access to Government Information, make available, on public request, individual responses.

The closing date for this consultation is 29th September 2015

Name:

Organisation (if applicable):

Address:

Please return completed forms to:

Victoria Griffiths

Department for Business, Innovation and Skills

Single Market Product Regulation

European Reform Directorate

4th Floor Spur 1

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Telephone: 020 7215 6212

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Please describe from the options below which best describes you as a respondent:

|  |  |
| --- | --- |
|  | Business representative organisation/trade body |
|  | Central government |
|  | Charity or social enterprise |
|  | Individual |
|  | Large business (over 250 staff) |
|  | Legal representative |
|  | Local Government |
|  | Medium business (50 to 250 staff) |
|  | Micro business (up to 9 staff) |
|  | Small business (10 to 49 staff) |
|  | Trade union or staff association |
|  | Other (please describe) |

Please also state which Directives you are primarily interested in:

### Questions asking you for your general views on the changes

**Question 1** - Do you expect any benefits from the proposed changes? If so, what would they be; what evidence do you have for them; and how great would they be?

**Comments:**

**Question 2** - Can you think of any possible unintended consequences as a result of these changes? If so, what are they?

**Comments:**

**Question 3** - Are there any areas covered by the new Directives on which it would be beneficial to have more guidance for consumers, importers and/or manufacturers? If so, please give details.

**Comments**:

**Question 4** – (a) Do you consider that the draft regulations (either individually or collectively) are effective and proportionate? If not, please explain why you think this is the case. (b) Do the draft regulations impose requirements which go beyond the requirements set out in the new Directives and which you consider to be disproportionate or unnecessary? If so, please explain why you think this is the case.

**Comments**:

### More specific questions about the requirements of the regulations and how they should be implemented, including on specific regulations

**Question 5 -** Should the template for the declaration of conformity be added as a Schedule to the regulations or should this cross-reference to the Annex to the Directive? Why?

**Comments:**

**Question 6 -** Should the Regulations cross-refer to the Annexes in the Directives or should the text of the Annexes be included (where possible) in Schedules to the Regulations? Why?

**Comments:**

**Question 7 -** The Directives require that instructions and safety information must accompany the product in a language which can be easily understood by consumers and end-users, as determined by the Member State concerned. Should the Regulations specify that for products made available to end-users in the United Kingdom, English is the language which can be easily understood to ensure greater clarity? Or would this be too restrictive?

**Comments:**

**Question 8 -** Should the new Regulations covering the different product strands all follow the same structure? Why?

**Comments:**

**Question 9** - Should provisions which are common to each of the Directives be implemented in exactly the same way (where possible) - e.g. using exactly the same language - in the various sets of regulations?

**Comments:**

**Question 10** - Do you agree with the Non Automatic Weighing Instruments (NAWI) and Measuring Instruments Directive (MID) draft regulations (where applicable) including the in-service control of individual measuring instruments on the UK market place? Please note that the provisions complement the safeguard clause of the Directives and are identical to those already in existence in the current legislation.

**Comments:**

**Question 11** - Do you agree with the proposal to align the requirements for gas and electricity meters with those of the other MID instruments, thereby allowing meters approved under national legislation to be put into use after 30th October 2016? This will allow meters held in stock by suppliers or asset owners to continue to be put into use after this date; thereby avoiding the need for suppliers and asset owners to dispose of these assets.

**Comments:**

**Question 12** - Can you provide an estimate of the cost saving by allowing these meters to continue to be put into use after 30th October 2016? If so, what is this based on?

**Comments:**

**Question 13** - Do you agree with the LVD draft regulations specifying the requirement for a safe connection to BS1363 style socket outlets and revoking the equivalent requirement in the Plugs and Sockets, etc (Safety) Regulations 1994 (SI 1994:1768)? Why?

**Comments:**

### Questions about the estimates of figures/costs we have used/are seeking more information about

1. When answering the questions in this section, please make clear which IA / sector you are referring to

**Question 14** - Do the Impact Assessments adequately reflect the effect of the new Directives?

**Comments:**

**Question 15** - Do you agree with our estimate of the number of businesses affected in each sector? Can you provide additional evidence?

**Comments:**

**Question 16** - Are you able to provide any evidence (quantified or otherwise) of the likely costs of the changes for the main affected groups i.e. manufacturers, importers or distributors? If so, what is this based on?

**Comments:**

**Question 17** - Do you agree with our estimate of the average costs (one-off and on-going) to business? Can you provide additional evidence to support your answer? If so, what is this based on?

**Comments:**

**Question 18** - Do you agree with our estimate of the average costs to Notified Bodies? Can you provide additional evidence to support your answer?

**Comments:**

**Question 19** - What is your estimate of the costs on a yearly basis for your business in complying with the Regulations, in terms of either additional time spent in complying with the regulations or financial costs? Please specify whether the costs have been calculated using additional time spent or financial costs. If using additional time spent please provide an estimate of the additional number of hours required alongside costs?

**Comments:**

1. Question 20 refers to all directives covered in the BIS Impact Assessment (i.e. all except for the Civil Uses Explosives Directive).

**Question 20** - If you are able to be more specific, can you give an estimate of the costs to business for (i) Familiarising themselves with the legislation; (ii) Holding the additional data; (iii) Obtaining new conformity assessment documentation; (iv) Post-marketing obligations?

**Comments:**

1. Question 21 refers to the Civil Uses Explosives Directive only.

**Question 21** (a) Do you agree with the assumptions made when estimating costs to manufacturers of the following? If not, why not? Could you provide alternative estimates? What are these based on:

* Familiarisation;
* conformity attestation;
* packaging;
* procedures when products pose a risk.

(b) Do you agree with the assumptions made when estimating costs to distributors and importers of the following? If not, why not? Could you provide alternative estimates? What are these based on?

* Familiarisation
* checking packaging and safety requirements
* taking action following receipt of non-compliant products

(c) Could you provide additional estimates of costs to manufacturers for translation of safety information? If so, what have you based these on?

(d) Could you provide additional estimates of costs to importers for annotating the explosives with their details? If so, what have you based these on?

**Comments:**

### Questions about penalties

**Question 22** - In order to implement the NLF Directives we must set effective, proportionate and dissuasive penalties for infringements. Should the new legislation have a consistent approach to penalties across all the implementing regulations?

**Comments:**

### Questions about redress

**Question 23** - Is the level of redress in the new legislation sufficient? Why?

**Comments:**

### General question

**Question 24** - Do you have any other comments that might aid the consultation as a whole?

**Comments:**

Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below.

Please acknowledge this reply

At BIS we carry out our research on many different topics and consultations. As your views are valuable to us, would it be okay if we were to contact you again from time to time either for research or to send through consultation documents?

Yes  No

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