



Department
for Business
Innovation & Skills



**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:

BIS

Victoria Griffiths
1 Victoria Street
London
SW1H 0ET

HSE

Explosives Policy Team
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Redgrave Court
Merton Road
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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.
2. 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.
3. 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.
4. 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.
5. 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

Name	“Old” Number	“New” Number
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

6. 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.
7. 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.
8. 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.
9. 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.
10. 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 <i>(there are 15 individual instrument regulations plus amendment regulations which will be revoked and replaced by</i>	Measuring Instruments 2014/32 EU

Existing Directive	Existing Legislation	New Directive
	<i>one omnibus regulation covering all instrument types).</i>	
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

11. 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.

12. This consultation will be relevant to:

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

13. 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

14. 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.
15. The consultation response form is available electronically on the consultation page: <https://www.gov.uk/government/consultations/eu-single-market-directives-alignment-with-new-legislation> (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: nfalignmentconsultation@bis.gsi.gov.uk

16. 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.
17. You may make printed copies of this document without seeking permission.

3. Confidentiality & Data Protection

18. 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.
19. 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

20. 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: nfalignmentconsultation@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

21. 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

22. Manufacturers will need to provide instructions and safety information with a product in a language which is easily understood by consumers and end-users

23. 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
24. Manufacturers will also need to ensure that the name and address of the manufacturer is indicated on the product or its packaging
25. 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

26. 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
27. They will be obliged to check that the manufacturer outside the EU has applied the correct conformity assessment procedure
28. In addition, they should check that products bear the CE marking and are accompanied by the required documents
29. Furthermore importers should ensure that the name and address of both the manufacturer and importer is indicated on the products or the packaging
30. 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

31. 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.
32. 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.
33. 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)

34. 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.
35. 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).
36. 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
37. 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

38. 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.
39. 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

40. 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

41. 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?

42. 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?

43. 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?

44. 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

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

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 Maritime 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
1 Victoria Street
London SW1H 0ET

Telephone: 020 7215 6212

email: nfalignmentconsultation@bis.gsi.gov.uk

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

45. 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:

46. 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:

47. 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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