BIS | Department for Business Innovation & Skills

PROPOSALS TO ALIGN NINE DIRECTIVES WITH THE NEW LEGISLATIVE FRAMEWORK

Consultation

JANUARY 2012

Contents

NLF ALIGNMENT PACKAGE – PUBLIC CONSULTATION - PROPOSALS TO ALIGN NINE DIRECTIVES WITH THE NEW LEGISLATIVE FRAMEWORK

1. Executive summary

1. This consultation seeks your views on the European Commission's Proposals to align a package of nine Directives to the New Legislative Framework for Community Harmonisation Legislation for Products (NLF), and in particular the provisions of Decision 768/2008/EC.

2. We are required under Government guidelines to consult with stakeholders that have an interest in the following sectors Low Voltage Directive (Electrical Equipment), Simple Pressure Vessels, Non-automatic Weighing Instruments, Civil Explosives, Equipment for Use in Explosive Atmospheres ("ATEX"), Lifts and their safety components, Measuring Instruments, Pyrotechnic Articles, and any products in regard to which electromagnetic compatibility is relevant.

3. The nine Proposals are:

   - Simple Pressure Vessels Directive: 2009/105/EC;
   - "ATEX" Directive: 94/9/EC (Equipment etc for Use in Potentially Explosive Atmospheres);
   - Pyrotechnic Articles Directive: 2007/23/EC ;
   - Civil Explosives Directive: 93/15/EEC;
   - Electromagnetic Compatibility Directive: 2004/108/EC;
   - Low Voltage Electrical Equipment Directive: 2006/95/EC;
   - Measuring Instruments Directive: 2004/22/EC;
   - Non-Automatic Weighing Instruments Directive: 2009/23/EEC (previously Directive 1990/384/EC); and
   - Lifts Directive: 1995/16/EC.

   See Annex 5 for links to copies of Regulation 765/2008/EC, Decision, 768/2008/EC and each of the proposals.

4. The alignment of the nine Directives in the package with the Decision has the following aims:

   - to address the number of non-compliant products that reach the market through improved traceability and clearer requirements on manufacturers, importers and distributors to co-operate with enforcement authorities;
   - to address inconsistent performance between Notified Bodies through a reinforced notification process;

- to address the complexity of the current legislation through alignment of commonly used definitions and certain aspects of the conformity assessment process.

5. The above aims help to take forward the BIS priority of removing government as an obstacle to growth while ensuring responsible corporate behaviour, through the creation of a positive business environment.

6. BIS has the policy lead on eight proposals, the Health and Safety Executive (Great Britain) and Northern Ireland Department of Justice (DOJ) lead on the Civil Explosives Directive.

7. We should welcome your observations in answer to the questions listed at section 9 below or on any other matter on which you might like to make an observation.

8. A list of contacts for the Alignment Package in general and specific contacts for each Directive within the Package can be found in Annex 6.

Issued: 13 January 2012

Respond by: 6 April 2012

2. Background

9. The UK was closely involved in developing the proposals for the New Legislative Framework for Community Harmonisation Legislation for products ("the NLF"), including the provisions of Decision 768/2008/EC ("the Decision"), and supported the adoption of the measure. The Government broadly supports the proposals in the Alignment Package, which we think are in line with the NLF. We are also mindful of the Decision's binding character on the Commission, Member States and the European Parliament. The Commission has to initiate proposals such as this to fulfil its obligations.

10. The Commission has always made clear that the proposals will be limited to alignment only and will not seek to amend the essential requirements of each Directive. The presumption is that such proposals will follow the provisions of the Decision unless a reasonable case can be made for departing from them. The additional obligations imposed by the Alignment Package are listed in section 5 of this document.

11. We are content that the proposals reflect the Commission's intention to align the Directives with the Decision and do not go beyond this remit. Given that the UK played a significant part in shaping the Decision, we think that we can broadly support the Commission's Proposals with only modest interventions needed to safeguard the UK's legitimate interests.

3. Rationale for legislation

12. Decision 768/2008/EC is binding upon the European Commission, the Member States and the European Parliament to whom it is addressed. It sets out a common framework for EU harmonised product legislation and when the Commission introduces proposals for alignment of specific Directives with the provisions in the Decision, Member States are then obliged to legislate to implement the revised Directives. Doing nothing is therefore not an option. Non-legislative means, by definition, cannot override the provisions of the existing legislation. Only legislative measures can bring about the alignment of the directives with the provisions of the Decision.

13. The EU Impact Assessment (IA) (see link at Annex 5) notes "If Economic Operators (manufacturers, importers, distributors) do not voluntarily mark their names and contacts on products or do not provide upon request information on the origin of the goods traded, market surveillance authorities will be unable to trace dangerous products and stop their supply to the market. Furthermore, the competitiveness of compliant firms may be damaged if they incur additional costs to align their conduct with best practices while non-compliant firms don't" (p. 39 EU Impact Assessment – "EU IA")

14. The EU IA also notes "the problem of complexity and inconsistencies throughout the directives cannot be satisfactorily addressed through non regulatory means. Guidance

documents can clarify unclear provisions but where the problems are rooted in differences in the legal provisions, guidance documents cannot prevail over these provisions" (p. 40 EU IA)

4. Problem:

15. The EU IA consultations have identified three main problems with regard to the functioning of the current legislation: "(1) non-compliance of significant number of products that reach the market, (2) unsatisfactory performance of certain Notified Bodies and (3) complexity of the current legislation".

16. In order to address these problems, the Alignment Package proposes that the following additional obligations are to be applied in each of the nine Directives in the Package.

5. Additional Obligations imposed through the Alignment Package:

Measures intended to address the problem of non-compliance:

Manufacturer obligations:

- To provide instructions and safety information in a language easily understood by consumers and end-users
- To check that products are identifiable and bear the CE marking accompanied by the required documents
- To ensure that products carry the name of the manufacturer and the importer (if relevant).
- To 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 (Article R2 of Annex I of the NLF Decision).

Importer obligations:

- To check that the manufacturer outside the EU has applied the correct conformity assessment procedure
- To check that products bear the CE marking accompanied by the required documents
- To ensure products carry the name of the manufacturer and the importer (if relevant).
- To keep a copy of the EC declaration of conformity and ensure that the technical documentation can be obtained when it is requested by authorities.
- To carry out same sample testing and product monitoring as applies to manufacturers. (Articles R4 in Annex 1 of the NLF Decision).

All Economic Operators; Manufacturers, importers and distributors, lift installers:

- Introduction of traceability requirements: ensure traceability of products throughout the whole distribution chain. Manufacturers and importers must put their name and address on the product or, where this is not possible, on the packaging or an accompanying document.
- Furthermore every economic operator must be able to inform the authorities of the economic operator from whom a product was purchased and to whom it was supplied.
- Reorganisation/streamlining of safeguard clause procedure (market surveillance): The new procedure ensures that the relevant enforcement authorities are informed about products presenting a risk to health or safety or public interest protection and that similar action is taken against that product in all Member States (Articles R31-33 in Annex 1 of the NLF Decision).

Measures intended to ensure the quality of the work performed by notified bodies (NBs):

- Reinforcement of the notification requirements for notified bodies: To be authorised to carry out conformity assessment activities under the directives, notified bodies must satisfy certain requirements. All notified bodies must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place 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 (Article R17 to R20 in Annex 1 of the NLF Decision).
- Revised notification process: Member States notifying a body must include information on the evaluation 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 (2 months) (Articles R22 and R23 in Annex 1 of the NLF Decision).
- Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of notified bodies): Specific requirements and obligations for notifying authorities are introduced (Articles R14, R15 in Annex 1 of the NLF Decision), 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 (Article R25 in Annex 1 of the NLF Decision).
- Information and other obligations for notified bodies**:** Notified Bodies must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other notified bodies 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 the sector, the complexity of the product technology, etc. (Article R28 in Annex 1 of the NLF Decision).

Measures intended to ensure more consistency among the directives

- Alignment of commonly used definitions and terminology: Definitions of common terms like “manufacturer”, “importer”, “placing on the market” set out in Article R2 of the NLF Decision are introduced into the directives concerned. Existing conflicting definitions are removed.
- 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. Enforcement Considerations

17. The application of article 15(3) and Articles 16-29 of Regulation (EC) 765/2008 is expressly provided for. These articles already apply as the Regulation is directly applicable. The effect is to make available to market surveillance authorities the power to take measures available under Directive 2001/95/EC (General Product Safety Directive) and to require Member States to organise and carry out market surveillance, comply with information obligations, employ investigative powers, powers to carry out restrictive measures, including those necessary for products presenting a serious risk, to exchange information via the Rapid Information Exchange System, ensure co-operation and exchange of information between Member States and the Commission, including cooperation with competent authorities in third countries and powers to control products entering the Community market.

18. The proposals allow for proportionate penalties to be imposed by Member States which can include both criminal and civil sanctions. The enforcement agency responsible will assess which compliance measures are most appropriate. This will usually be carried out on a case by case basis in response to each complaint and allows for flexibility regarding the methods to be used to demonstrate compliance. In these cases, manufacturers and others, however, may need to involve a notified body authorised to conduct conformity assessments on products to be placed on the market in order to demonstrate compliance with the relevant directive.

19. Subject to consultation in due course with the relevant Market Surveillance Authorities (MSA), we envisage that enforcement will continue to be carried out by MSA that currently have the responsibilities under the existing legislation. These include - as is appropriate to the relevant existing UK legislation - the Health & Safety Executive, local trading standards offices, OFCOM, equivalent authorities in Northern Ireland and, in certain limited respects, the National Measurement Office, Department for Transport, and BIS itself. It is not expected that the costs for these authorities will rise significantly; the allocation of resources required to facilitate effective enforcement will be a matter for those concerned.

7. How to respond

20. 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 response form and, where applicable, how the how the views of members were assembled.

    A copy of the Consultation Response form can be found at Annex 4, or downloaded from http://www.bis.gov.uk/assets/biscore/business-sectors/docs/p/12-550rf-proposals-align-directives-with-new-legislative-framework-form

    If you decide to respond this way, the form can be submitted by letter, fax or email to:

    John O'Shea

    Electronics, Materials, Chemicals & Product Regulation,

    Department for Business,

    Innovation & Skills,

    4th Floor,

    1 Victoria Street,

    London SW1H 0ET.

    Fax: 020 7215 6862

    Email: mailto:nlf.consultation@bis.gsi.gov.uk

8. Additional copies

21. You may make copies of this document without seeking permission. Further printed copies of the consultation document can be obtained from:

    BIS Publications Orderline

    ADMAIL 528

London SW1W 8YT

Tel: 0845-015 0010

Fax: 0845-015 0020

Minicom: 0845-015 0030

www.bis.gov.uk/publications

An electronic version can be found at:

www.bis.gov.uk/assets/biscore/business-sectors/docs/p/12-550-proposals-align-directives-with-new-legislative-framework-consultation

Other versions of the document in Braille, other languages or audio-cassette are available on request.

9. Confidentiality & Data Protection

22. 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.

23. 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.

10. Help with queries

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

John O'Shea

Electronics, Materials, Chemical & Product Regulation

Department of Business, Innovation and Skills

1 Victoria Street, London, SW1H 0ET

Tel: 020 7215 1285

Email mailto:nlf.consultation@bis.gsi.gov.uk

A copy of the Code of Practice on Consultation can be found at Annex 1.

11. Consultation questions

For each question, please consider whether the proposed measures are reasonable and appropriate in every case and whether any time periods specified are reasonable.

Additional Obligations imposed through the Alignment Package:

Measures intended to address the problem of non-compliance:

Question 1

Manufacturer obligations -

For the proposed legislation that impacts on your sector do think that it includes the relevant provisions of 768/2008/EC particularly as regards the obligations that are appropriate in relation to the products within scope?

- To provide instructions and safety information in a language easily understood by consumers and end-users
- To check that products bear the CE marking accompanied by the required documents
- To carry the name of the manufacturer and the importer (if relevant).
- To 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 (Article R2 of Annex I of the NLF Decision).

Question 2

Importer obligations -

For the proposed legislation that impacts on your sector do think that it includes the relevant provisions of 768/2008/EC particularly as regards the obligations that are appropriate in relation to the products within scope?

- To check that the manufacturer outside the EU has applied the correct conformity assessment procedure
- To check that products bear the CE marking accompanied by the required documents
- To ensure products carry the name of the manufacturer and the importer (if relevant).
- To keep a copy of the EC declaration of conformity and ensure that the technical documentation can be obtained when it is requested by authorities.
- To carry out same sample testing and product monitoring as applies to manufacturers. (Articles R4 in Annex 1 of the NLF Decision).

Question 3

All Economic Operators; Manufacturers, importers and distributors, lift installers:

For the proposed legislation that impacts on your sector do think that it includes the relevant provisions of 768/2008/EC that are appropriate in relation to the products within scope particularly as regards the following points:

- Introduction of traceability requirements: ensure traceability of products throughout the whole distribution chain.
- Manufacturers and importers must put their name and address on the product or, where this is not possible, on the packaging or an accompanying document.
- 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.
- Reorganisation/streamlining of safeguard clause procedure (market surveillance): The new procedure ensures that the relevant enforcement authorities are informed about dangerous products and that similar action is taken against that product in all Member States (Articles R31-33 in Annex 1 of the NLF Decision).

Measures intended to ensure the quality of the work performed by notified bodies (NBs):

Question 4

For the proposed legislation that impacts on your sector do think that it includes the relevant provisions of 768/2008/EC that are appropriate in relation to the products within scope particularly as regards the following obligations:

- Reinforcement of the notification requirements for notified bodies: To be authorised to carry out conformity assessment activities under the directives, notified bodies must satisfy certain requirements. All notified bodies must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place 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 (Article R17 to R20 in Annex 1 of the NLF Decision).
- Revised notification process: Member States notifying a body must include information on the evaluation 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 (2 months) (Articles R22 and R23 in Annex 1 of the NLF Decision).
- Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of notified bodies): Specific requirements and obligations for notifying authorities are introduced (Articles R14, R15 in Annex 1 of the NLF Decision), 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 (Article R25 in Annex 1 of the NLF Decision).
- Information and other obligations for notified bodies: Notified bodies must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other notified bodies 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 the sector, the complexity of the product technology, etc. (Article R28 in Annex 1 of the NLF Decision).

Measures intended to ensure more consistency among the directives

Question 5

For the proposed legislation that impacts on your sector do think that it includes the relevant provisions of 768/2008/EC that are appropriate in relation to the products within scope particularly as regards the following obligations:

- Alignment of commonly used definitions and terminology: Definitions of common terms like “manufacturer”, “importer”, “placing on the market” set out in Article R2 of the NLF Decision are introduced into the directives concerned. Existing conflicting definitions are removed.
- 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.

Question 6

For the proposed legislation that impacts on your sector do think that it includes the relevant provisions of 768/2008/EC particularly as regards the Safeguard Procedures (Chapter R5 of the Decision) in relation to products within scope? Do think that what is proposed is reasonable?

Conformity assessment procedures

Question 7

For the proposed legislation that impacts on your sector do think that it strikes the right balance in terms of aligning the conformity assessment procedures to the relevant provisions of 768/2008/EC and making proper allowance of the particular characteristics within the scope of the specific legislation?

Other matters

Question 8

a) For the legislation that impacts on your sector or overall, do you have any comments on the draft Impact Assessment included with this consultation?

b) Do you have any information, such as costs or other figures that you can share?

c) Do you agree with the benefits and burdens identified and with the costs allocation in each case? If not, please explain why.

d) Are the transitional periods identified for complying with the new provisions appropriate in relation to the products in each sector as regards the changes that might be necessary to documentation and stocks complying with the old provisions that are held by manufacturers before being placed on the market?

Question 9

Do you have any observations or proposals to make in addition to ones in answer to those above of either a general or a sector specific nature?

Questions related to specific Directives

Pyrotechnic Articles Directive: 2007/23/EC;

Question 10

(Relates to Q 3 on traceability). In the case of pyrotechnic articles alone there is an additional requirement to include a number to identify and link the article to its technical documentation. Is this necessary given the range of pyrotechnic articles in categories 1 – 4 within scope ?

Question 11

(Relates to Q 5 on definitions and terms). There is no reference to an authorised representative in the Pyrotechnics Directive. Is this appropriate given the nature of the products and their marketing?

Question 12

In relation to pyrotechnic articles, the provisions on the operation of the Explosives Committee have been adapted to the new rules on delegated acts laid down in Article 290 of the Treaty on the Functioning of the EU and to the new provisions on implementing acts laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers[1].Are these correctly applied or should they be reassessed in the light of the other changes ?

Electromagnetic Compatibility Directive: 2004/108/EC & Low Voltage Electrical Equipment Directive: 2006/95/EC;

Question 13

(Relates to Q7 on conformity assessment). In the case of the EMC Directive, there is provision for notified body conformity assessment while there is none in the Low Voltage Directive. Is this appropriate given the nature of products within scope of both directives?

[1] OJ L 55, 28.2.2011, p. 13.

Simple Pressure Vessels Directive: 2009/105/EC;

Question 14

In Art 1.1 b) of the proposal, the term "assemblies" has been changed to "components". Do you think that this is a significant change?

Question 15

Annex 1 of the proposal has a number of changes of language e.g. "rupture" becomes "fracture"; "failure" becomes "bending rupture" and again in Annex III "proof stress" becomes "proof strength". Do you think that these changes are significant?

12. What happens next?

25. After the closing date the responses will be collated and summarised. These will be published on the BIS website. The Government will aim to publish the results of this consultation and provide a response by 29 June 2012.

26. The Better Regulation Executive Code of Practice on consultation states that decisions in the light of the consultation should be made public promptly with a summary of views expressed and reasons given for decisions finally taken. This should be on the BIS website, including a link from the central BIS consultation web pages, with paper copies of the summary of responses made available on request.

Annex 1: The Consultation Code of Practice Criteria

1. Formal consultation should take place at a stage when there is scope to influence policy outcome.
2. Consultation should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.
3. Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.
4. Consultation exercise should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.
5. Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.
6. Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.
7. Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

Comments or complaints

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:

Sameera de Silva,

BIS Consultation Co-ordinator

Department for Business Innovation and Skills

1 Victoria Street,

London

SW1H 0ET

Telephone: 020 7215 2888

or e-mail to: Sameera.De.Silva@bis.gsi.gov.uk

Annex 2: List of Individuals/Organisations consulted

ABCB	British Fluid Power Association	Conformance Ltd
ABS Group	British in Vitro Diagnostics Association	Construction Equipment Association
Agricultural Engineers Association	British Industrial Truck Association	Cosmetic Toiletry and Perfumery Association
AJA Registrars Ltd	British Inspecting Engineers Ltd	David Burdett
AJV Regulatory Services	British Retail Consortium	DEFRA
Allcord Ltd	British Safety Council	Department for Communities and Local Government
Allied Approvals Limited	British Safety Industry Federation	Department for Transport
Approved Cables Initiative	British Toy and Hobby Association	Department of Enterprise, Trade & Investment Northern Ireland
Arrowhead Industrial Services Limited	British Water	Department of Health
ASCB(E)	Bruel & Kjaer UK Ltd	Department of Health (MHRA)
Association of British Certification Bodies	BSI Management Systems Poland	Det Norske Veritas BV (DNV)
Association of British Healthcare Industries	BSI Management Systems UK	DNV Certification Ltd
Association of Manufacturers of Domestic Appliances (AMDEA)	BSI Product Services	Dr Clifton Martin
AstraZeneca UK Ltd	Bureau Veritas Quality International Ltd	EAICEM
Astrium Products	Bureau Veritas UK Limited	Economic Development Office

AV Technology Ltd	Campden & Chorleywood Food Research Association Group	Edward Haynes
Barry Cartman	Cardiff Trading Standards	EIEMA
BM Polyco Ltd	Cast Metals Federation	Electrical Contractor's Association
Bolle Safety	Catering Equipment Suppliers Association	Electrical Safety Council
Boots UK Limited	CBI	Elfab Ltd
BPMA	CEHOG Consumer Protection Sub-Group	EMC Test Laboratories Association
BRE	CERAM	EMEA
British Approvals Board of Telecommunications	Certification International (UK) Ltd	Engineering and Machinery Alliance
British Approvals Service for Cables	Chartered Institution of Building Services Engineers	Engineering Equipment and Material Users Association
British Association of Leisure Parks, Piers & Attractions	Chartered Quality Institute	Environment Agency
British Board of Agrément	Chemical Industries Association	EQUITOY
British Cables Association	CHKS	Expert Ease International
British Chambers of Commerce	CIPS	FBE Management Ltd
British Compressed Air Society	Civil Aviation Authority	Federation of Small Businesses
British Electrotechnical and Allied Manufacturers Association	Coherent Tech Ltd	FETA

Fire Brigades Union	ISOQAR	National Security Inspectorate
Foodstandards Agency	Jamie Collard	Nemko Ltd

Forecourt Equipment Federation	Jerry Harrington	Nigel Cadwallader
Gambica	John Liscombe Ltd	Norman Greig
GeoLang Ltd	Joint Accreditation System of Australia and New Zealand	NSF-CMi Certification Ltd
GL Noble Denton	Kellogg Brown & Root Limited	Nuclear Electric
Graham Hart (Process Technology) Ltd	Lighting Association Ltd	Occupational Safety and Health Editorial
Greenham	Lighting Industry Federation	OFCOM
Halfords	Lloyd's Register Quality Assurance	ORR
Hartley Jones Innovation Ltd	Lloyd's Register Verification Limited	Pall Corporation
Health and Safety Executive (HSE)	Local Better Regulation Office	Panasonic UK
Health Protection Agency	LRQA Centre	Pera
Hewlett-Packard	Lubrizol Limited	Peter Morris
HMRC	Manufacturing Technologies Association	Pharmaceutical & Medical Device Technology Consultants
Home Office	MCA	Portable Electric Tool Manufacturers Association
Ian Andrews	MCGA	Qualidoc
Ian Roberts	Metra Martech	Risk Management Services
ICMA	MHRA	Road Haulage Association Ltd
IFIA	MICA Associates	Rotating Electrical Machines Association (REMA)
IIOC	Michael Clarke	RWE Npower Plc
INSPEC International Ltd	Mike Tebbutt	Safety Assessment Federation

Institute of Occupational Medicine	MIRA	SATRA Technology
Intellect	MOD	SBAC
International Register Certified Auditors	Moody International Ltd	SBGI
International Federation of Inspection Agencies (IFIA)	Mr J C Pyle	Security Systems and Alarms
International Lift & Escalator Consultants	Ms Caroline Warne	SGS UK Ltd
International Powered Access Federation	Ms Kerry Somerset	SIRA
International Society for Quality in Health Care	National Association of Goldsmiths	Small Electrical Appliance Marketing Association
Intertek Labtest UK Limited	National Measurement Office	SMI
Invest Northern Ireland	National Physical Laboratory	SMMT

Society of British Water Industries	TUV SUD Product Service	VCA
Society of Martime Industries	TUV UK Ltd	VCA Dangerous Goods Office
Spirax Sacro Ltd	TWI Certification Ltd	VOSA
Stephen Phillips	UK Cares	WEB Processing (M/C) Ltd
Technology International (Europe) Ltd	UK Cleaning Products Industry Association	Which?
Trades Union Congress	UKAS	Wood Panel Industries Federation
Trading Standards Institute	UL International (UK) Ltd	Worldwide Quality Assurance Limited
TUV Product Services	University of Portsmouth	

Annex 3: Impact Assessment Checklist of the Alignment Package

PROPOSALS FOR 9 DIRECTIVES TO BE ALIGNED TO EU DECISION 768/2008/EC ON A COMMON FRAMEWORK FOR THE MARKETING OF PRODUCTS AND TO CERTAIN PROVISIONS OF EU REGULATION 765/2008/EC - "THE NEW LEGISLATIVE FRAMEWORK" FOR COMMUNITY HARMONISATION LEGISLATION FOR PRODUCTS ("NLF")

Checklist for analysis on EU proposals – Overall alignment package

Title of EU proposal: Alignment Package **Lead dept/agency:** BIS **Other** HSE, Dft **Date:** 1 November 2011	**Lead policy official:** Richard Lawson, Richard.Lawson@bis.gsi.gov.uk x1469

What are the potential impacts of the Commission proposal on the UK?

Background/Policy Objectives

To implement the provisions of the EU New Legislative Framework's Decision 768/2008/EC on a common framework for the marketing of goods and repealing Council Decision 93/46/EEC together with reiterating Member States' duties to fulfil the market surveillance provisions contained in EU Regulation 765/2008/EC setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation 339/93. The objective of the New Legislative Framework (NLF) is to facilitate the functioning of the internal market for goods and to strengthen and modernise the conditions for placing a wide range of products on the EU market. It builds upon existing systems to introduce clear EU policies which will strengthen the application and enforcement of internal market legislation. The NLF objectives are to ensure that products available in Europe meet a high level of protection to public interests like health and safety, consumer protection or environmental protection and to ensure the free movement of products.

The key features that will be aligned in nine Directives (Low Voltage Directive, Simple Pressure Vessels Directive. Non-automatic Weighing Instruments Directive, Civil Explosives Directive, ATEX Directive, Lifts Directive, Measuring Instruments Directive, Electromagnetic Compatibility Directive,

Pyrotechnic articles Directive) under the alignment package will include definitions, obligations of economic operators (EOs) (including manufacturers, authorised representatives, importers and distributors), conformity of the product, notification of conformity assessment bodies, conformity assessment procedures and safeguard procedures.

Rationale for legislation

Decision 768/2008/EC is binding upon the European Commission, the Member States and the European Parliament to whom it is addressed. It sets out a common framework for EU harmonised product legislation and when the Commission introduces proposals for alignment of specific Directives with the provisions in the Decision, Member States are then obliged to legislate to implement the revised Directives. Doing nothing is therefore not an option. Non-legislative means, by definition, cannot override the provisions of the existing legislation. Only legislative measures can bring about the alignment of the directives with the provisions of the Decision.

The EU IA notes "If EO do not voluntarily mark their names and contacts on products or do not provide upon request information on the origin of the goods traded, market surveillance authorities will be unable to trace dangerous products and stop their supply to the market. Furthermore, the competitiveness of compliant firms may be damaged if they incur additional costs to align their conduct with best practices while non-compliant firms don't" (pg 39 EU IA)

The EU IA also notes "the problem of complexity and inconsistencies throughout the directives cannot be satisfactorily addressed through non regulatory means. Guidance documents can clarify unclear provisions but where the problems are rooted in differences in the legal provisions, guidance documents cannot prevail over these provisions" (pg40 EU IA)

Problem:

The EU IA consultations have identified three main problems with regard to the functioning of the current legislation: "(1) non-compliance of significant number of products that reach the market, (2) unsatisfactory performance of certain Notified Bodies and (3) complexity of the current legislation".

Additional Obligations imposed through the Alignment Package:

Measures intended to address the problem of non-compliance:

Manufacturer obligations:

- To provide instructions and safety information in a language easily understood by consumers and end-users
- To check that products bear the CE marking accompanied by the required documents
- To carry the name of the manufacturer and the importer (if relevant).
- To 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 (Article R2 of Annex I of the NLF Decision).

Importer obligations:

- To check that the manufacturer outside the EU has applied the correct conformity assessment procedure
- To check that products bear the CE marking accompanied by the required documents
- To ensure products carry the name of the manufacturer and the importer (if relevant).
- To keep a copy of the EC declaration of conformity and ensure that the technical documentation can be obtained when it is requested by authorities.
- To carry out same sample testing and product monitoring as applies to manufacturers. (Articles R4 in Annex 1 of the NLF Decision).

All Economic Operators; Manufacturers, importers and distributors, lift installers:

- Introduction of traceability requirements: ensure traceability of products throughout the whole distribution chain. Manufacturers and importers must put their name and address on the product or, where this is not possible, on the packaging or an accompanying document.
- 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.
- Reorganisation/streamlining of safeguard clause procedure (market surveillance): The new procedure ensures that the relevant enforcement authorities are informed about dangerous products and that similar action is taken against that product in all Member States (Articles R31-33 in Annex 1 of the NLF Decision).

Measures intended to ensure the quality of the work performed by notified bodies (NBs):

- Reinforcement of the notification requirements for notified bodies: To be authorised to carry out conformity assessment activities under the directives, notified bodies must satisfy certain requirements. All notified bodies must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place 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 (Article R17 to R20 in Annex 1 of the NLF Decision).

- Revised notification process: Member States notifying a body must include information on the evaluation 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 (2 months) (Articles R22 and R23 in Annex 1 of the NLF Decision).
- Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of notified bodies): Specific requirements and obligations for notifying authorities are introduced (Articles R14, R15 in Annex 1 of the NLF Decision), 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 (Article R25 in Annex 1 of the NLF Decision).
- Information and other obligations for notified bodies**:** Notified bodies must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other notified bodies 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 the sector, the complexity of the product technology, etc. (Article R28 in Annex 1 of the NLF Decision).

Measures intended to ensure more consistency among the directives

- Alignment of commonly used definitions and terminology: Definitions of common terms like "manufacturer", "importer", "placing on the market" set out in Article R2 of the NLF Decision are introduced into the directives concerned. Existing conflicting definitions are removed.
- 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

AFFECTED GROUPS:

Indicate the main groups you think are likely to be affected and whether these are in the public/private/voluntary sector/consumers. If the proposal is likely to affect business, indicate the:

- Sectors involved will be those covered in the following directives: Low Voltage Directive, Simple Pressure Vessels Directive. Non-automatic Weighing Instruments Directive, Civil Explosives Directive, ATEX Directive, Lifts Directive, Measuring Instruments Directive, Electromagnetic Compatibility Directive, Pyrotechnic articles Directive
- These sectors account for approximately £13bn GVA, 36bn turnover and about 11k businesses (excluding lifts). Further details regarding assumptions on the data are included in the Impact Assessments for each proposal – see in particular that for Simple Pressure Vessels.
- The EU IA conducted a Small & Medium Enterprise (SME) survey there was "no indication that the selected option might result in a disproportionate burden for SME. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle" (EU IA pg 120).

COSTS & BENEFITS:

Alignment of sector directives make obligations for manufacturers, importers and distributors formally enforceable but will not lead to additional adjustments for business that have already been 'acting responsibly' (pg 42 EC IA). See table 1 below.

Costs

- Traceability requirements could increase operating costs &/ administrative burden for manufacturers and importers as manufacturers' names, addresses as well as the products' identifying batches/serial numbers are required to be included on products. In addition an economic operator (EO) must keep records of the EO from whom he purchases a product and to whom he supplies a product. However manufacturers are already obliged to include their name under existing directives. Some will already include identifying serial numbers of products also. Similar traceability requirements also exist in respect of products that are also consumer products within scope of the General Product Safety Directive. EC IA survey results: 55% general Economic Operators (EO) suggests moderate impact on costs, 1-5% expect significant costs increase. These will be one-off costs.
- Post marketing obligations (e.g. sample testing, keeping register of complaints and defective products) will, if appropriate, need to be established if not already in place (42% of general EO and 23% of SME attribute no / no significant cost increase to these elements whilst 30% of EOs and 18% of SME a significant increase. These will be one-off costs.
- Of the EOs and SMEs who provided estimates of magnitude of increased costs, most EOs estimated the increase in cost up to 5% of current operating costs and SMEs estimated a 6-10% increase.

Benefits:

- Economic impacts: better functioning of the internal market, competitiveness of EU-firms, simplification of the regulatory environment. Potential cost savings from cost of gathering information on reliability of products supplied by importers/distributors and cost of insurance to cover risks due to non-compliant products.

- Social impacts: benefit to health and safety of consumers and workers through reducing the number of non-compliant products on the market (via clear obligations for importers and distributors/ market surveillance/traceability requirements)

- Environmental impacts: reduction in risk of environmentally unfriendly goods and prevention of fire, explosions and accidents leading to environmental risks.

Table 1 : EC assessment of impacts

	ECONOMIC IMPACTS						SOCIAL IMPACTS	ENVIRONMENTAL IMPACTS	OTHER IMPACTS
	Internal market	Competitiveness	Costs and admin. Burdens for EO or NB	Public authorities		Third countries relations	Consumers and users	Public health	Restriction of polluting goods/ Likelyhood of environm. Risks	Simplification
Option 2: Alignment via non-legislative measures	(+)	(-)/(+)	(- / -) if follow guidance	(0)	(0)	(0)	(+)	(+)	(+)	(0)
Option 3: Alignment via legislative measures	(+++)	(++)/(+++)	(- / -)	(++)/(+++)	(0/ -)	(0/+)	(+++)	(++)/(+++)	(++)	(++)/(+++)

(key: the more the plus or negative signs the bigger the positive or negative impact, 0 = neutral impact)

Source: EU IA 2011

We conclude that the overall costs and benefits are modest. The benefits are harder to quantify than the costs, which are, in part, one-off costs arising from the need to adapt to the NLF but there is cautious optimism in business that the Proposals will succeed in achieving the long term aim of improving the internal market in products through more effective market surveillance, better regulation of notified bodies and more effective legislative harmonisation.

ENFORCEMENT:

Impact on **enforcement bodies**.

- EU IA notes that EO obligations "may even reduce authorities' investigation costs (e.g. the traceability obligation will facilitate the identification of EO having marketed non-compliant products)".
- Enforcement will be assisted by the obligation in most cases to use authorised notified bodies (NBs) to demonstrate compliance. Existing NBs that do not meet the new requirements will not be notified and will no longer be able to operate – this would mitigate against unfair competition amongst NBs. The EC IA notes a moderate (temporary) increase in administrative burden on notified bodies from :

- a need to request new notification (this would only be a burden for those not meeting requirements)
- produce updated evidence to show compliance with the requirements (e.g. accreditation and/or other certificates showing professional qualifications); Accreditation is not/not mandatory but many NBs are already accredited.

Ongoing costs:

- stronger cross border co-operation will mean there will be information obligations e.g. transmitting information from NBs on refusals, restrictions, suspensions and withdrawals of certificates, negative conformity assessment results.

The EU IA notes "the strengthening of NB (Notified Body)[2] requirements is not expected to lead to any additional operating costs and/or administrative burden on NB that act in accordance with recognised professional standards" (pg 44). The UK has a relatively more competitive market for NBs.

Table 2: Number of Notified Bodies in the UK:

DIRECTIVE	NB
Pyrotechnic	0
Civil Expl	1
EMC	26
LVD	20
ATEX	7
MID	48
NAWI	94
SPVD	9
Lifts	7

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no

[2] Notified Body: organisation that has been accredited by a Member State to assess whether a product meets certain preordained standards

independent domestic legislation in any of the relevant fields. The existing Regulations implementing the current Directives will need to be revoked and replaced by new Regulations implementing the revised Directives. Copy out will be used in transposing the Directives wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals – Low Voltage

Title of EU proposal: Low Voltage Directive 2006/95/EEC **Lead dept/agency:** BIS **Other depts/agencies with an interest:** HSE **Date:** 1 November 2011	**Lead policy official:** Richard Harris, Richard.Harris@bis.gsi.gov.uk, 020 7215 1325

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- The proposal extends responsibilities to include all economic operators in the supply chain. This change will not give rise to any additional costs as the current Directive has been implemented in part under the Consumer Protection Act which imposes obligations on these parties.
- Requirements regarding identification of the products is tightened up. This should involve little change as the General Product Safety Directive places similar requirements on consumer products falling within the scope of this Directive. In addition there are similar requirements for record keeping under the GPSD.
- The proposal omits the function of notified bodies in the conformity assessment process entirely. Currently notified bodies are infrequently used so the change is unlikely to have a significant impact on notified bodies. There will be a loss of income to some extent.
- Enforcement agencies will need updated training on the revised requirements.
- The LVD sector (+ EMC) equates to approximately £11bn GVA and £31bn in turnover these are the largest sectors of the other 8 directives. There are approximately 9.9k enterprises employing 210k people. (ABI, 2009 data).

COSTS & BENEFITS:

- Traceability requirements could increase operating costs and or administrative burden for manufacturers and importers as manufacturers' names, addresses as well as the products' identifying batches/ serial numbers are required to be included on products. In addition an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product. However these requirements already exist in respect of products that are also consumer products within scope of the General Product Safety Directive so the impact of these requirements is absorbed in relation to these products. The

industry response at this stage did not specifically address the questions of the costs traceability. However, costs associated with these requirements are expected to be marginal and if further evidence indicates otherwise, we will report accordingly.

- Similarly post marketing obligations (sample testing, keeping a register of complaints and defective products) are already required under the GPSD but will need to be established in respect of non-consumer products if appropriate. The industry's response to our enquiries did not specifically address the questions of the costs of these post-marketing obligations. The impact is however expected to be marginal and if further evidence indicates otherwise, we will report accordingly.

- A new directive number might lead to costs being incurred for manufacturers and notified bodies necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number. There will be a transitional period before these requirements will come into force so any alterations could be incorporated more broadly into periodic updating, hence any additional cost should be marginal.

- All 20 Notified bodies will cease to be authorised in respect of the LVD as they will not have a function. It should be noted there will be loss of current revenue to these bodies. As the Notified Bodies are usually used as test houses rather than notified bodies any loss would be down to loss of prestige by not being a Notified Body.

- Specifically addressing the duties of those in the supply chain across the Union will facilitate market surveillance of goods in the internal market – with potential positive implications on competition as all in the supply chain will have duties of due diligence and responsibility for ensuring product is in conformity.

- Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.

- It is expected there will be some benefit from clarification and harmonisation of definitions for business across Member States.

- The costs are likely to be marginal and mainly one-off. Benefits are more long term.

ENFORCEMENT:

- One-off training costs and updating costs to enforcement agencies – estimated by Health

and Safety Executive (HSE) to be approximately £5k.

- HSE have estimated benefits to enforcement agency from tightened traceability requirements leading to small savings in administration of hundreds of pounds.

- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that enforcement agency will be able to target more directly those infringing the requirements.

- In response to the informal BIS consultation, HSE suggested that tightened traceability requirements and the changes to NB will lead to very little in the way of savings "due to the low volume of work in this area, and not having problems previously with traceability of such industrial goods." The main benefit will be clear duties placed on distributors thus making it easier to take action at source, rather than only at end user stage. Savings in administration in HSE due to this effect will be low and in the order of hundreds of pounds only".

- It is expected that there will be one off training costs (fitted into existing updating) for HSE product safety teams and some revision of the website and published information. However, this will be done as part of a routine update, and will as far as possible link to BIS guidance. Total one off costs will be in order of a few thousand pounds, ~ £5k. It is expected that ongoing costs will be minimal if in fact there are any.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no independent domestic legislation in this field. The existing Regulations implementing the current Low Voltage Directive will need to be revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals - Simple Pressure Vessels

Title of EU proposal: Simple Pressure Vessels Directive 2009/105/EC **Lead dept/agency: BIS** **Other depts/agencies with an interest: HSE** **Date:** 1 November 2011	**Lead policy official:** Andrew Lunnon, Andrew.Lunnon@bis.gsi.gov.uk, 020 7215 0158

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- Economic operators (manufacturers, importers and distributors) in the Simple Pressure Vessels (SPV) sector will be affected.
- Notified bodies will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.
- Enforcement agencies will need updated training on the revised requirements.
- Simple Pressure Vessels are included in the wider pressure equipment sector (mostly covered by the Pressure Equipment Directive, which is not in the Alignment Package) GVA, for the wider pressure equipment sector, is approx £1.7bn, with a turnover of £4bn and 805 companies, employing ~28k people (ABI, 2009 data). The sector comprises mostly of SMEs, with a few larger multi-nationals that make SPV equipment as part of a wider product range.

COSTS & BENEFITS:

- A new directive number might lead to costs being incurred for manufacturers and Notified bodies necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number. There will be a transitional period before these requirements will come into force hence any alterations might be incorporated more broadly into periodic updating, so any additional cost may be mitigated.

- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.

- Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.

- Traceability requirements could increase operating costs and or administrative burden for manufacturers and importers as manufacturers' addresses as well as the products' identifying batches/ serial numbers are required to be included on products. In addition an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product. These requirements already exist in respect of products that are also consumer products within scope of the General Product Safety Directive so the impact of these requirements is absorbed in relation to these products. However, most products in the SPV sector are not consumer products. The industry response at this stage did not specifically address the questions of the costs traceability. However, costs associated with these requirements are expected to be marginal and if further evidence indicates otherwise, we will report accordingly.

- Similarly post marketing obligations (sample testing, keeping a register of complaints and defective products) are already required under the GPSD but will need to be established, where appropriate, in respect of non-consumer products. Again the industry's response to our enquiries did not specifically address the questions of the costs of these post-marketing obligations. The impact is however expected to be marginal and if further evidence indicates otherwise, we will report accordingly.

- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.

- The costs are likely to be marginal and mainly one off. Benefits more long term.

ENFORCEMENT:

- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased cooperation between NBs for equipment placed on the market.
- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/importer) may also bring some minor benefits in that HSE will be able to target more directly those infringing the requirements.
- There may be costs associated with updating the training of HSE inspectors, although this would probably be included as part of a routine update, thus minimising costs.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no independent domestic legislation in this field. The existing Regulations implementing the current SPV Directive will need to be revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date

Checklist for analysis on EU proposals - Non-automatic weighing instruments

Title of EU proposal: Non-automatic Weighing Instruments Directive 2009/23/EC **Lead dept/agency:** BIS **Other depts/agencies with an interest:** **Date:** 1 November 2011	**Lead policy official:** Peter Edwards & Sue Billing peter.edwards@nmo.gov.uk 020 8943 7298 sue.billing@nmo.gov.uk 020 8943 7277

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- Industry that will be affected include those in sectors for non-automatic weighing instruments used for weighing for commercial transactions including making up of pre-packages and calculating price
- Public authorities and commercial organisations will be affected where instruments are used for the collection of tolls, tax and tariffs etc., the application of laws, in medical practice for diagnosis and treatment and in pharmacies
- Notified bodies will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.
- Enforcement agencies will need updated training on the revised requirements.
- Measuring instruments account for approximately £3bn in GVA and £7.6bn in turnover, with approximately 2.3k companies and 53k employees (ABI, 2009 data)

COSTS & BENEFITS:

- Traceability requirements could increase operating costs and or administrative burden for manufacturers and importers as manufacturers' names, addresses as well as the products' identifying batches/ serial numbers are required to be included on products. In addition an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product. The industry response at this stage did not specifically address the questions of the costs traceability. However, costs associated with these requirements are expected to be marginal, as existing level of compliance is already considered high, and if further evidence indicates otherwise, we will report accordingly.

- In response to the consultation carried out by BIS, Industry representatives noted a new directive number would lead to costs being incurred and necessitate the re-drafting and re-issue of documents and manuals to include the revised number. However these requirements don't come into force until after the transition period so could be incorporated more broadly into periodic updating, in which case any cost implication would be marginal.
- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.
- The terms of type approval have been widened to permit type examination of documentation as well as the non-automatic measuring instrument (Module B – allowing alternative assessment of technical documentation without examination of a specimen/design type). This change will give greater flexibility and the potential for small cost savings to be made if that conformity assessment option is selected. However there is no requirement to deviate from existing trade practices where such a change would give rise to additional costs.
- Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.
- It is expected there will be some benefit from clarification and harmonisation of definitions for business across Member States.
- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits
- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.

ENFORCEMENT:

- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased cooperation between NBs for equipment placed on the market.
- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that enforcement agency will be able to target more directly those infringing the requirements.

- There may be costs associated with updating the training of enforcement agency inspectors, although this would probably be included as part of a routine update, thus minimising costs.
- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will be more frequent.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no

independent domestic legislation applicable to instruments first placed on the market after 30 October 2016 in this field. The existing regulations implementing the current NAWI Directive will need to be revoked and replaced by new regulations implementing the revised directive. Copy out will be used in transposing the directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals – Civil Explosives

Title of EU proposal: Civil Explosives Directive 93/15/EC **Lead dept/agency:** HSE **Other depts/agencies with an interest:** **Date:** 1 November 2011	**Lead policy official:** David Pascoe david.pascoe@hse.gsi.gov.uk 01519514241

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS: :

- Manufacturers, distributors and importers of commercially used explosive substances and articles
- There is one Notified Body which will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.
- Enforcement agencies will need updated training on the revised requirements.
- The approximate GVA for the manufacture of explosives is ~ £0.1bn, with a turnover of £0.2bn and approximately 10 enterprises (prodcom category; 'manufacture of explosives', ABI 2009 data).

COSTS & BENEFITS:

- Traceability requirements could increase operating costs and or administrative burden for manufacturers and importers as manufacturers' names, addresses as well as the products' identifying batches/ serial numbers are required to be included on products. In addition an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product. The industry response at this stage did not specifically address the questions of the costs traceability. However, costs associated with these requirements are expected not to be large, as compliance is already considered to be high, if further evidence indicates otherwise, we will report accordingly.

- A new directive number might lead to costs being incurred for manufacturers and the Notified Body necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number. There will be a transitional period before these requirements

will come into force hence any alterations could be incorporated more broadly into periodic updating, so any additional cost should be marginal.

- The same applies for record keeping i.e. the duty for EOs to retain Technical File and Declaration of Conformity for the manufacturer/importer to retain documents for 10 years. Some of the products under Civil Explosives are likely to have a lifespan of less than 10 years. The requirement to retain technical file for such a period is a burden in some cases. Overall the additional storage cost is likely to be small.

- The recast (within the testing modules) requires that a specimen of the product is examined by the Notified Body before accreditation. The current Directive allows accreditation on the basis of documentary evidence which is then followed up by site audit. HSE estimate the inspection of a specimen will necessitate an additional 3-6 hours work over and above the audit currently required for the manufacturing process. For reasons of probity and safety it is the Explosives Notified Body (ENB's) policy to send two assessors. The rate charged for this work is £135/hour per assessor. Assuming it takes 3 to 6 hours costs per product are estimated at £810 to £1620 (i.e. 3 x 2 x 135 = £810 and 6 x 2 x 135 = £1620).

  In the last five years there have been 8 applications for CE marking of products from UK manufacturers with sites based in the UK and 2 from UK manufacturers based in Europe (both from Eire). We have assumed a one off additional cost per product due to the recast Directive of:

  Sites within UK (calculated for two assessors) £1150 - (single night's additional accommodation (£250), subsistence for two days (£300), travel (£400) and admin support for visit (£200 - 2 hrs @£100/hr).

  Sites within Europe (calculated for two assessors) £2150 - (based on two nights' additional accommodation (£500), subsistence for three days (£450), travel (£800) and admin support for visit (£400 - 4 hrs @£100/hr).

  Therefore the estimated additional costs for sites within UK are **£1960** and **£2770** and for sites within Europe of **£2960** and **£3770.**

  Over the last 5 years there has been an annual average of 1.6 applications for the accreditation of a new product on UK sites (total 8) and 0.4 applications for sites within Europe (total 2). This allows the calculation of minimum and maximum one off additional total costs for UK businesses as a result of the recast of £4320 and £5940 annually.

- Requirements on the instructions and safety information are a new legal duty but it is

expected manufacturers do this any way, hence it can be assumed there is no extra cost.

- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when Explosives Notified Bodies are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.

- Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.

- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.

- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits

- It is expected there will be some benefit from clarification and harmonisation of definitions for business across Member States.

- Overall the sample testing within the pre-marketing obligation makes up the largest proportion of expected costs – these costs will be on going. Benefits are more long term.

ENFORCEMENT:

- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that HSE will be able to target more directly those infringing the requirements.

- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased cooperation between NBs for equipment placed on the market.

- There may be costs associated with updating the training of enforcement agency inspectors, although this would probably be included as part of a routine update, thus minimising costs.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no

independent domestic legislation in this field. The existing Regulations implementing the current Civil Use Explosives Directive will need to be either amended or revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals – ATEX

Title of EU proposal: Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (ATEX) Directive 94/9/EC **Lead dept/agency:** BIS **Other depts/agencies with an interest:** HSE **Date:** 1 November 2011	**Lead policy official:** Andrew Lunnon, Andrew.Lunnon@bis.gsi.gov.uk, 020 7215 0158

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- Regulations apply to all equipment intended for use in explosive atmospheres, whether electrical or mechanical, and also to protective systems. Economic operators (manufacturers, distributors and importers) in this sector will be affected.
- Notified bodies (NBs) will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.
- Enforcement agencies will need updated training on the revised requirements.
- It is not possible to estimate the size of this sector as it isn't captured in official data - it'll cover for instance the adaptation of existing machinery for use in explosive atmospheres rather than the original machinery. The EU IA estimates the turnover – if apportioned on the basis of the UK population as a proportion of the EU population (12%) turnover in the UK could be around £0.3bn. It is estimated that approximately 90% of the companies in this sector are SMEs.

COSTS & BENEFITS:

- A new directive number might lead to costs being incurred for manufacturers and Notified bodies necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number. There will be a transitional period before these requirements will come into force hence any alterations may be incorporated more broadly into periodic updating, so any additional cost could be mitigated. Consultation with NB's suggests costs

incurred on updating documentation to reflect the new number could equate to approx £50k (for a Notified Body) including presumed update required for ATEX certificates. [3]

- Duty on EOs to retain Technical File and Declaration of Conformity adds a requirement for the manufacturer/importer to retain documents for 10 years. This is not a new requirement, except for those companies choosing the Unit Verification route to compliance. For these companies, the requirement might entail an additional storage cost, albeit probably a small one. Unit Verification is used for compliance assessment of "one-off" pieces of equipment and so is less commonly used.

- Traceability requirements could increase operating costs and or administrative burden for manufacturers and importers as an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product. While the industry's response to our enquiries was specific and well-costed, it did not specifically address the questions of the costs of traceability. However, costs associated with this requirement are expected to be marginal and if evidence indicates otherwise, we will report accordingly.

- Post marketing obligations (sample testing, keeping a register of complaints and defective products) will need to be established, where appropriate. Again the industry's response to our enquiries did not specifically address the questions of the costs of these post-marketing obligations. The impact is however expected to be marginal and if further evidence indicates otherwise, we will report accordingly.

- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.

- Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.

- It is expected there will be some benefit from clarification and harmonisation of definitions for business across MEMBER STATES.

- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/

[3] ~£50k = £10k (to update training modules in PowerPoint / hardcopy) + update website (£5k) + update hardcopy literature (£5k) + £5-£20k (explaining to customers etc) + £10k (software costs assuming the directive needs a different identifier in the middle of the certificate number) + £2k (certificate pro-formas)

importer) may also bring some minor benefits, in that the right person in the supply chain who does not conform will be more traceable.

- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.

ENFORCEMENT:

- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased cooperation between NBs for equipment placed on the market.
- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that HSE will be able to target more directly those infringing the requirements.
- There may be costs associated with updating the training of enforcement agency inspectors, although this would probably be included as part of a routine update, thus minimising costs.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no independent domestic legislation in this field. The existing Regulations implementing the current ATEX Directive will need to be revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals - Lifts

Title of EU proposal: Lifts Directive 95/16/EC **Lead dept/agency:** BIS **Other depts/agencies with an interest:** HSE **Date:** 1 November 2011	**Lead policy official:** Richard Lawson Richard.Lawson@bis.gsi.gov.uk x1469

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- Manufacturers, distributors and importers in the lift sector are likely to be affected.
- Notified bodies will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.
- Enforcement agencies will need updated training on the revised requirements.
- It is estimated by an industry association that the industry employs approximately 10,500 persons in total. The value of sector during 2009 was estimated at £332m. They also estimate that the majority of companies are medium sized.

COSTS & BENEFITS:

- A new directive number leading to costs being incurred for manufacturers (and Notified bodies) necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number were the main costs indentified by industry via consultation. There will be a transitional period before these requirements will come into force hence any alterations could be incorporated more broadly into periodic updating, so any additional cost should be marginal. An industry trade body provided preliminary/rough cost estimates to be in the order of £3.2 million. A breakdown of costs is provided below

Assuming each member would have the following information that was making reference to the old directive No 95/16/EC, 89 documents would have to change.

Document required for updating	No. per company
Company web page	1
Product brochures assumed	3
Information manual	6
Master declaration of conformity	1
Type test certificates	5
Factory order sheets	5
Service manuals	10
Training material revisions	20
Information sheet	15
Site hand books	3
Tool box talks	10
Risk assessment	10
Total	89

Assuming it takes 1 hour made up of 30 minutes to locate and modify the document plus 30 minutes to reload to systems or distribute to, web sites, factory etc. Taking 1 hour per 89 document and costing 89 hours per company. Some companies make and print their own forms but most get brochures printed at high cost estimated on average to be £184. This is made up of mostly professional labour £100+ £84. The cost of ordering new stock of forms and brochures, destroying old stock and notifying staff of stock change and reason were not itemised but included within the overall estimate.

The total cost to industry is therefore

= £184 X 89 docs x 158 members = £2,587,408

To estimate training costs it is estimated that 10.5k staff are employed by industry as only a limited number of persons in any company need to understand the changes to legislation it is assumed only 20% need to be trained (ie. 2100 staff need to be trained) it is estimated that training costs £320 per person – so the cost of training per person is estimated at £320 x 2100 = £672k

Total costs of updating documentation and training equate to 672'000 + 2'587'408 = approx £3.2m.These costs would be one off (likely to be incurred in first two years)

- Traceability requirements to carry the address of the manufacturer/ UK importer that necessitate changes to labels or data plates are not new, as they are already imposed under the Machinery Directive. The requirements will be new for safety components (unless they too qualify as machinery). In addition an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product, the impact will be dependent on existing level of compliance, which is likely to be positive as this would constitute as part of general record keeping by business. However, while the industry's response to our enquiries was specific and well-costed, it did not specifically address the questions of the costs of traceability. Therefore, although we anticipate that costs associated with these requirements will be marginal, if further evidence indicates otherwise, we will report accordingly.
- Post marketing obligations (e.g. sample testing, keeping a register of complaints and defective products) are already required under the GPSD but will need to be established, where appropriate, in respect of non-consumer products. Again the industry's response to our enquiries did not specifically address the questions of the costs of these post-marketing obligations. The impact is, however, expected to be marginal and if further evidence indicates otherwise, we will report accordingly.
- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.
- Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.
- The trade association for lifts suggest that in the long run it is expected there will be some benefit from clarification and harmonisation of definitions for business across Member States
- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.
- The costs are likely to be marginal and mainly one off. Benefits more long term.
- Industry association also suggests that "anything less than a legal requirement will, we assume, just be ignored". This is likely to be because industry are used to the existing directives and are unlikely to change behaviour if not legally binding

ENFORCEMENT:

- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that the enforcement authority will be able to target more directly those infringing the requirements.
- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased cooperation between NBs for equipment placed on the market.
- There may be costs associated with updating the training of enforcement agency inspectors, although this would probably be included as part of a routine update, thus minimising costs.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no independent domestic legislation in this field. The existing Regulations implementing the current Lifts Directive will need to be revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals – Measuring Instruments

Title of EU proposal: Measuring Instruments Directive 2004/108/EC **Lead dept/agency:** BIS **Other depts/agencies with an interest:** **Date:** 1 November 2011	**Lead policy official: Peter Edwards** [peter.edwards@nmo.gov.uk, 020 8943 7298 sue.billing@nmo.gov.uk, 020 8943 7277

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- Manufacturers, distributors and importers of measuring instruments are likely to be affected.
- Notified bodies will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.
- Enforcement agencies will need updated training on the revised requirements.
- Measuring instruments account for approximately £3bn in GVA and £7.6bn in turnover, with approximately 2.3k companies and 53k employees (ABI, 2009 data)

COSTS & BENEFITS:

- A new directive number might lead to costs being incurred for manufacturers and Notified bodies necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number. There will be a transitional period before these requirements will come into force hence any alterations could be incorporated more broadly into periodic updating, so any additional cost should be marginal.

- Duty on EOs to retain Technical File and Declaration of Conformity adds a requirement for the manufacturer/importer to retain documents for 10 years. This might entail an additional storage cost, albeit probably a small one
- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.

- Could be marginal benefits to organisations wishing to become notified bodies from clearer indication of the notification process
- Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.

- It is expected there will be some benefit from clarification and harmonisation of definitions for business across Member States.

- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.
- The costs are likely to be marginal and mainly one off. Benefits are more long term.
- There may also be financial savings for notified bodies due to traceability requirement and increased cooperation. There will also be additional business for Notified bodies.

ENFORCEMENT:

- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that the enforcement authority will be able to target more directly those infringing the requirements.
- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased cooperation between NBs for equipment placed on the market.
- There may be costs associated with updating the training of enforcement agency inspectors, although this would probably be included as part of a routine update, thus minimising costs.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no independent domestic legislation in this field. The existing Regulations implementing the current MID Directive will need to be revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals – Electromagnetic Compatibility

Title of EU proposal: Electromagnetic Compatibility Directive 2004/108/EC **Lead dept/agency:** BIS **Other depts/agencies with an interest:** OFCOM, NMO **Date:** 1 November 2011	**Lead policy official:** Richard Harris, Richard.Harris@bis.gsi.gov.uk, x 1325

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- Manufacturers, distributors and importers of equipment within the scope of the Directive are likely to be affected.
- Notified bodies will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations. We note the proposal for LVD is to remove the function of notified bodies: it would be inconsistent not to deal with EMC Notified Bodies in the same way as LVD.
- Enforcement agencies will need updated training on the revised requirements.
- Business in the electro-technical sector (e.g. electric welding and soldering tools, electric domestic appliances, computers and other information processing equipment, battery operated equipment etc) will be affected. These sectors including many of those that are covered in the Low Voltage Directive (+EMC) accounts for approximately £11bn GVA and £31bn in turnover these are the largest sectors of the other 8 directives. There are approximately 9.9k enterprises employing 210k persons. (ABI, 2009 data).

COSTS & BENEFITS:

- Traceability requirements could increase operating costs and /or administrative burden for manufacturers and importers as manufacturers' names, addresses as well as the products' identifying batches/ serial numbers are required to be included on products. In addition an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product. However these requirements already exist in respect of products that are also consumer products within scope of the General Product Safety Directive so the impact of these requirements is absorbed in relation to these products. Industry response did not specifically address the questions of the costs of traceability. Therefore, although we anticipate that costs associated with these requirements will be marginal, if further evidence indicates otherwise, we will report accordingly.

- Similarly post marketing obligations (sample testing, keeping a register of complaints and defective products) are already required under the GPSD but will need to be established in respect of non-consumer products, where appropriate. The impact is expected to be marginal as much of this is currently done anyway. Again the industry's response to our enquiries did not specifically address the questions of the costs of these post-marketing obligations. The impact is, however, expected to be marginal and if further evidence indicates otherwise, we will report accordingly.

- A new directive number might lead to costs being incurred for manufacturers and notified bodies necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number. There will be a transitional period before these requirements will come into force hence any alterations could be incorporated more broadly into periodic updating, so any additional cost should be marginal.

- Strengthened obligations on information sharing among Notified Bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.

- There could be marginal benefits to organisations wishing to become Notified Bodies from clearer indication of the notification process

- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.

- It is expected there will be some benefit from clarification and harmonisation of definitions for business across Member States.

- The costs are likely to be marginal and mainly one-off. Benefits more long term.

ENFORCEMENT:

- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that the enforcement authority will be able to target more directly those infringing the requirements.

- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased cooperation between NBs for equipment placed on the market.
- There may be costs associated with updating the training of enforcement agency inspectors, although this would probably be included as part of a routine update, thus minimising costs.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no independent domestic legislation in this field. The existing Regulations implementing the current Directive will need to be revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Checklist for analysis on EU proposals – Pyrotechnic Articles

Title of EU proposal: Pyrotechnic articles Directive 2007/23/EC **Lead dept/agency:** BIS **Other depts/agencies with an interest:** HSE, Trading Standards **Date:** 1 November 2011	**Lead policy official:** Christine Knox christine.knox@bis.gsi.gov.uk 020 7215 3465

What are the potential impacts of the Commission proposal on the UK?

AFFECTED GROUPS:

- Manufacturers, distributors and importers of sectors including fireworks, theatrical pyrotechnic articles, automotive pyrotechnic articles (e.g. gas generators used in airbags)
- Notified bodies will be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.
- Enforcement agencies will need updated training on the revised requirements.
- The approximate GVA for the manufacture of explosives is ~ £0.1bn, with a turnover of £0.2bn and approximately 20 enterprises (prodcom category; 'manufacture of explosives', ABI 2009 data).
- The industry response from BIS informal consultation suggested that "the vast majority of the pyrotechnic industries in UK are SMEs, with many being micro businesses".

COSTS & BENEFITS:

- Traceability requirements could increase operating costs and or administrative burden for manufacturers and importers as manufacturers' names, addresses as well as the products' identifying batches/ serial numbers are required to be included on products. The response from CBI Explosives Industry Group suggested that there will be a cost involved in implementing the new obligation to label the pyrotechnic with a number linking it to technical information. In addition an economic operator must keep records of the economic operators from whom he purchases a product and to whom he supplies a product. Compliance with the general traceability requirements is already necessary in relation to products that are consumer products within scope of the GPSD (with the exception of the requirement for a registration number), but will need to be established in respect of non-consumer products, where appropriate. Industry response did not specifically address the questions of the costs of traceability. Therefore, although we anticipate that costs associated with these requirements will be marginal, if further evidence indicates otherwise, we will report accordingly.

- Part of the existing conformity assessment procedure for pyrotechnic articles is to verify that the labelling is correct (Module B). Traceability requirements will lead to increased costs especially for small businesses (which make up the majority of businesses in this sector) if changes to labels or data plates are required (existing directive already includes basic traceability regs e.g. for name and address of manufacturer or importer) – this *may* mean that the label will have to be replaced with one bearing the unique identifier. Assuming the unique identifier is that relating to the article type then the cost should not be significant; if it should also identify the batch then the cost will be larger as many pyrotechnic articles are produced in relatively small batch sizes, incurring one off costs.

- There will be a duty for EOs to retain Technical File and Declaration of Conformity for the manufacturer/importer to retain documents for 10 years. This is a current requirement except for products that are assessed under module G. In future manufacturers using Module G will also have to retain documentation for 10 years. Some of the products under Pyrotechnics are likely to have a lifespan of less than 10 years. The requirement to retain technical file for such a period would be a burden in these cases. Industry response did not address the question of costs associated with this requirement, however the additional data collection / storage cost is expected to be marginal, if further evidence indicates otherwise, it'll be reported accordingly.

- A new directive number might lead to costs being incurred for manufacturers and notified bodies necessitating the re-drafting and re-issue of documents [and manuals] to include the revised number. There will be a transitional period before these requirements will come into force hence any alterations could be incorporated more broadly into periodic updating, so any additional cost should be marginal.

- Strengthened obligations on information sharing among notified bodies (e.g. on withdrawn certificates etc) will lead to some increase in ongoing costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.

- Could be marginal benefits to organisations wishing to become notified bodies from clearer indication of the notification process

- Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market – with potential positive implications on competition.

- It is expected there will be some benefit from clarification and harmonisation of definitions for business across Member States.

- There will be a need for industry and government to ensure importers are aware of changes to legislation – NBs response to consultation suggest that some importers are unaware of requirements.

ENFORCEMENT:

- Some Trading Standards departments have indicated they do not receive a large number of complaints from consumers and they do not therefore envisage much in the way of financial benefit accruing to them from the proposed amendment.
- There may be some minor financial savings in enforcement costs due to the improved traceability requirements and increased co-operation between NBs for equipment placed on the market.
- Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/ importer) may also bring some minor benefits in that the enforcement authority will be able to target more directly those infringing the requirements.

LEGAL IMPLEMENTATION/COPY-OUT:

- The proposal is a Single Market harmonisation measure and there is therefore minimal flexibility for Member States to pursue alternatives in transposition. There is no independent domestic legislation in this field. The existing Regulations implementing the current Directive will need to be revoked and replaced by new Regulations implementing the revised Directive. Copy out will be used in transposing the Directive wherever possible. However, it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty etc. It is not proposed to go beyond the minimum requirements of the Directive in the UK implementing legislation.

Ministerial sign-off:

I have read the analysis above of the potential impacts of this proposal and I am satisfied that, given the significance of the proposal, the time and evidence available, and the uncertainty of the outcome of negotiations, it represents a proportionate view of possible impacts.

Signed by the responsible Minister: Date:

Annex 4: The Alignment Package Public Consultation: 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 6/4/2012.

Name:

Organisation (if applicable):

Address:

Please return completed forms to:

John O'Shea

Department for Business, Innovation & Skills

Orchard 1, 4th Floor

1 Victoria Street

London SW1H 0ET

Telephone: 020 7215 1285

Fax: 020 7215 6862

Email: mailto:nlf.consultation@bis.gsi.gov.uk

Please tick a box from the list of options below that 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)
	Small business (10 to 49 staff)
	Micro business (up to 9 staff)
	Trade union or staff association
	Other (please describe)

Question 1

Manufacturer obligations -

For the proposed legislation that impacts on your sector do think that it fairly reflects the relevant provisions of 768/2008/EC?

Comments:

Question 2

Importer obligations -

For the proposed legislation that impacts on your sector do think that it fairly reflects the relevant provisions of 768/2008/EC ?

Comments:

Question 3

All Economic Operators; Manufacturers, importers and distributors, lift installers -

For the proposed legislation that impacts on your sector do think that it fairly reflects the relevant provisions of 768/2008/EC?

Comments:

Question 4

Measures intended to ensure the quality of the work performed by notified bodies (NBs) -

For the proposed legislation that impacts on your sector do think that it fairly reflects the relevant provisions of 768/2008/EC?

Comments:

Question 5

Measures intended to ensure more consistency among the directives -

For the proposed legislation that impacts on your sector do think that it fairly reflects the relevant provisions of 768/2008/EC?

Comments:

Question 6

For the proposed legislation that impacts on your sector do think that it fairly reflects the relevant provisions of 768/2008/EC particularly as regards the Safeguard Procedures?

Comments :

Question 7

Conformity assessment procedures -

For the proposed legislation that impacts on your sector do think that it strikes the right balance in terms of aligning the conformity assessment procedures to the relevant provisions of 768/2008/EC and making proper allowance of the particular characteristics within the scope of the specific legislation?

Comments :

Question 8

a) For the legislation that impacts on your sector or overall, do you have any comments on the draft Impact Assessment included with this consultation?

b) Do you have any information, such as costs or other figures that you can share?

c) Do you agree with the benefits and burdens identified and with the costs allocation in each case? If not, please explain why.

d) Are the transitional periods identified for complying with the new provisions appropriate in relation to the products in each sector as regards the changes that might be necessary to documentation and stocks complying with the old provisions that are held by manufacturers before being placed on the market?

Comments :

Question 9

Other matters -

Do you have any observations or proposals to make in addition to ones in answer to those above of either a general or a sector specific nature?

Comments :

Questions related to specific Directives

Pyrotechnic Articles Directive: 2007/23/EC;

Question 10

(Relates to Q 3 on traceability). In the case of pyrotechnic articles alone there is an additional requirement to include a number to identify and link the article to its technical documentation. Is this necessary given the range of pyrotechnic articles in categories 1 – 4 within scope ?

Comments

Question 11

(Relates to Q 5 on definitions and terms). There is no reference to an authorised representative in the Pyrotechnics Directive. Is this appropriate given the nature of the products and their marketing?

Comments

Question 12

In relation to pyrotechnic articles, the provisions on the operation of the Explosives Committee have been adapted to the new rules on delegated acts laid down in Article 290 of the Treaty on the Functioning of the EU and to the new provisions on implementing acts laid down in Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers[4].Are these correctly applied or should they be reassessed in the light of the other changes ?

Comments

Electromagnetic Compatibility Directive: 2004/108/EC & Low Voltage Electrical Equipment Directive: 2006/95/EC;

Question 13

(Relates to Q7 on conformity assessment). In the case of the EMC Directive, there is provision for notified body conformity assessment while there is none in the Low Voltage Directive. Is this appropriate given the nature of products within scope of both directives?

4 OJ L 55, 28.2.2011, p. 13.

Comments

Simple Pressure Vessels Directive: 2009/105/EC;

Question 14

In Art 1.1 b) of the proposal, the term "assemblies" has been changed for "components". Do you think that this is a significant change?

Comments

Question 15

Annex 1 of the proposal has a number of changes of language e.g. "rupture" becomes "fracture"; "failure" becomes "bending rupture" and again in Annex III "proof stress" becomes "proof strength". Do you think that these changes are significant?

Comments

Do you have any other comments that might aid the consultation process as a whole?

Please use this space for any general comments that you may have, comments on the layout of this consultation would also be welcomed.

Annex 5: Links to copies of legislation

The Commission's NLF pages on its website contain links to the texts of Decision 768/2008/EC, Regulation 765/2008/EC, the nine proposals and the Commission's Impact Assessment for the Package.

The index page with links to this information, plus the outcome of the Commission's consultations with various sets of stakeholders can be found at: http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm .

Annex 6: Contacts for further information

Enquiries to:

On the Alignment Package in general:

- Richard Lawson, richard.lawson@bis.gsi.gov.uk
  020 7215 1469

On points about specific Directive Proposals:

- Low Voltage Directive 2006/95/EEC: Richard Harris, Richard.Harris@bis.gsi.gov.uk, 020 7215 1325

- Simple Pressure Vessels Directive 2009/105/EC: Andrew Lunnon, Andrew.Lunnon@bis.gsi.gov.uk, 020 7215 0158

- Non-automatic Weighing Instruments Directive 2009/23/EC: Peter Edwards & Sue Billing: peter.edwards@nmo.gov.uk, 020 8943 7298 sue.billing@nmo.gov.uk, 020 8943 7277

- Civil Explosives Directive 93/15/EC: David Pascoe david.pascoe@hse.gsi.gov.uk 01519514241

- Pyrotechnic Articles Directive: 2007/23/EC: Christine Knox: christine.knox@bis.gsi.gov.uk; 020 7215 3465

- Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (ATEX) Directive 94/9/EC: Andrew Lunnon, (as above)

- Lifts Directive 95/16/EC: Richard Lawson (as above)

- Measuring Instruments Directive 2004/22/EC: Peter Edwards & Sue Billing (as above)

- Electromagnetic Compatibility Directive 2004/108/EC: Richard Harris (as above)

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