

**CONSULTATION ON PROPOSALS
TO ALIGN NINE DIRECTIVES WITH
THE NEW LEGISLATIVE
FRAMEWORK: GOVERNMENT
RESPONSE**

JULY 2012

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Consultation on Proposals to align nine Directives with the New Legislative Framework: Government Response

Introduction

The Consultation was launched on 13 January 2012 to seek 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, published in November 2011. This consultation closed on 6 April 2012. Informal consultations have also taken place both before and after this formal consultation, including a stakeholder meeting that took place on 22 February.

The nine Proposals in the alignment package are:

- Simple Pressure Vessels Directive (SPV): 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 (EMC): 2004/108/EC;
- Low Voltage Electrical Equipment Directive (LVD): 2006/95/EC;
- Measuring Instruments Directive (MID): 2004/22/EC;
- Non-Automatic Weighing Instruments Directive (NAWI): 2009/23/EEC (previously Directive 1990/384/EC); and
- Lifts Directive: 1995/16/EC.

The Government would like to thank all those who responded to the consultation. We appreciate the time you have taken to let us have comments.

Executive summary

The Government has received twenty-one responses to the Consultation.

The responses were largely supportive of the proposals, but a number of issues and concerns were raised, some limited to specific proposals, others applicable to all of the nine.

The main issues raised in the response to the consultation were:

- A need for clarity on a number of issues, including transitional periods, definitions (in some Directives), labelling (of Pyrotechnics) and roles of different economic operators;
- Provisions for a single Declaration of Conformity covering all Directives that apply to a product could be burdensome for manufacturers and importers;
- Requirement for a colour photograph of the product to be provided in the Declaration of Conformity for the LVD would be burdensome and is beyond the scope for alignment;
- There should be no additional burdens on users of equipment covered by these proposals, including taxi drivers using meters covered by MID;
- Change of Directive numbers will lead to burdensome changes of documentation;
- The proposed changes to the role of Notified Bodies under the Low Voltage and EMC Directives;
- Changes in terminology in parts of the SPV Directive could be significant and lead to confusion; respondents believe that they are also beyond the scope of alignment;

The Government has some sympathy for a number of issues identified by respondents:

- We share the concerns over the clarity in certain areas and will seek to ensure that these points are addressed through improved drafting or guidance;
- We will seek to ensure that the requirement for a single Declaration of Conformity is clarified;
- The proposal in the LVD for the DoC to include a colour photograph of the product is too burdensome and beyond the scope of alignment;
- The changes should not impact on users of products; in response to specific questions, taxi drivers will not be affected by the changes to MID.
- We will seek to clarify what is required in relation to the need to amend documentation and product labelling with the new Directive numbers;
- Under the LVD it is true that there is no longer an option to use a Notified Body, but manufacturers are free to use an accredited assessment body if they wish.
- We believe that the changes in terminology in the SPV go beyond the scope of alignment;

Background

This consultation is to inform the development of the Government's negotiation strategy for the package of nine proposals through discussions in the EU Council Working Groups and the European Parliament. The Government has taken part in a number of meetings where the draft proposals have been discussed in detail, these meetings will continue into the autumn. It is the Commission's intention that the formal texts of the proposals will be agreed and published by the end of the year.

Our approach in developing the UK lines for negotiation has also included informal consultation and face to face meetings with stakeholders as part of an ongoing dialogue that will continue throughout the EU negotiation process. BIS held a stakeholder consultation meeting on the package in February 2012. Many of the stakeholder views submitted as part of this formal written consultation have been reinforced through the consultation meeting and other contacts. We have also received information and views outside this formal consultation.

All views, however we receive them, are considered when we are developing UK lines for the negotiation of the texts. However, it should be noted that it is not possible for BIS to change the proposals to take into account the concerns raised in the consultation as this is not within our power. In addition, it is Government policy that UK regulations implementing of EU Directives should not be “gold-plated”, therefore we will be bound by the agreed texts and will not be permitted to add unilateral provisions to the UK implementation. We will ensure that the concerns and comments we have received are presented to other stakeholders during the negotiations so that any changes that may be needed can be considered. We are unable to guarantee the outcome of discussions or that particular issues will be resolved.

The discussions in the Council Working Group are confidential and so this consultation response cannot disclose full details of the UK line, but we have addressed the points raised by respondents in as much detail as we are able to within these constraints.

Northern Ireland

In parallel with this consultation, the Department of Justice in Northern Ireland held a separate consultation on the proposals covering Civil Explosives and Pyrotechnics. The consultation ran from 10 February to the 4 May 2012. The response to this will be available at www.dojni.gov.uk.

Responses received

Although there was a relatively low response rate, the 21 responses received covered a wide range of interests. The table below shows the distribution of the respondents and a full list of respondents can be found at Annex A of this document. The responses covered the most of the questions asked in the consultation document and were given either in the context of a specific proposal or cross-cutting to cover all nine proposals.

Business representative organisation/trade body	7
Individual	3
Large business (over 250 staff)	3
Legal representative	0
Local Government	2
Medium business (50 to 250 staff)	1
Small business (10 to 49 staff)	0
Micro business (up to 9 staff)	2
Notified Body	2
Other (please describe)	1

Summary of responses and Government response

Question 1-3: Economic operators' obligations (Manufacturers, importers, distributors, installers). For the proposed legislation that impacts on your sector do think that it fairly reflects the relevant provisions of 768/2008/EC?

Increased regulatory burdens

Some respondents were concerned that the implementation of the Directives in UK law should avoid excessive bureaucracy generated by the requirements for traceability etc.

Government response:

We will seek to negotiate the texts in a way that minimises burdens on all concerned, in keeping with the Government's Better Regulation policy.

Marking of products with the manufacturer's name and address:

Some respondents asked for the option of replacing the postal address with a web address, this would save room on labels and enable extra information to be made available should it be needed.

Government response:

We understand why some respondents would prefer the option of using a web address, particularly as labelling space can be at a premium on some products. However, this goes

beyond the scope of alignment. In addition, a physical address is the preferred route of the market surveillance bodies for any enquiries or questions relating to the product. In terms of restricted space for some products, it is clear that the name and address can be shown on the product or if not possible the packaging or accompanying label. There is the option to use a web address as well as, but not instead of a postal address.

NAWI should include a definition of “putting into use”:

One respondent said that obligations with regard to “making available on the market” and “placing on the market” are defined but “putting into use” has not been defined in the NAWI re-cast.

Government response:

The term “putting into use” does not appear in the NAWI Directive or the NLF re-cast proposal. The expression used is ‘putting into service’ which is not an NLF definition and therefore as it was not defined in the original Directive it is not possible to draw up a definition as part of this alignment exercise. The Commission’s [“Blue Guide”](#)¹ gives guidance on the concept of putting into service/use and will be updated to reflect the changes introduced by the NLF alignment.

When a product is deemed to have been placed on the market and the roles of different economic operators:

Concern was expressed by a number of respondents, including manufacturers, market surveillance bodies and others, that adequate information should be available to explain the role of economic operators. This is especially important for those whose role has been formalised or enhanced in the alignment package (such as importers and distributors).

Government response:

We agree that information should be available in good time for the various parties involved to understand what is expected of them before the requirements enter into force. The European Commission has agreed that an update of the “Blue Guide” will be produced. The Government will also revise the UK guidance on each of the regulations implementing the amended Directives.

Single Declaration of Conformity:

This was an area of concern for a number of respondents who thought that a requirement for a single Declaration of Conformity (DoC) covering all Directives that apply to a product could be burdensome for manufacturers and importers, especially if that DoC has to be amended every time a new standard becomes available. Respondents thought that for some products covered by a number of Directives, it could mean that the DoC would be in an almost constant state of revision and the increased need for updating would be very time consuming and costly.

¹ The Guide to the Implementation of Directives Based on New Approach and Global Approach

Government response:

It is the Government's view that manufacturers have the responsibility of ensuring compliance of products with the essential requirements of all applicable directives and presenting a single declaration of conformity (DoC) in respect of the product. One way of ensuring conformity may be the use of standards published in the OJ which confer a presumption of conformity with the essential requirements. When these standards are replaced by new standards and are no longer published in the OJ, the presumption of conformity no longer applies but we believe that if the manufacturer is satisfied that compliance with the old standard meets the essential requirements, the manufacturer may continue to use the old standards and to cite reference to these standards in the DoC. There is no need for the manufacturer to issue a new DoC. We believe that in these circumstances Article R10 of Decision 2008/768/EC does not require the manufacturer to re-test the product to the new standards and replace the references in the DoC with the new standards simply because the old ones have been updated or are no longer published in the OJ. If the manufacturer chooses to use the new updated standards, he will need to reflect this in an amended DoC.

We will seek clarity on the DoC requirement in Article 10 of the Decision and if necessary, we will seek to agree amendments and/or revised guidance to make clear the duties of manufacturers and importers.

Requirement for a colour photograph of the product to be provided in the Declaration of Conformity for the LVD:

A number of respondents believed that this would be costly to implement as most DoCs are produced in black and white, so the change to colour would entail a redesign of existing DoCs and more expensive printing processes. Respondents also said that some products, particularly consumer products change in appearance regularly, but the specification remains the same. At the moment, a change in appearance doesn't affect the DoC, but the requirement to provide a colour image would mean more frequent (and time consuming) changes to the documentation.

Government response:

The Government believes that this additional requirement would be beyond the scope of alignment. We also agree that it would be burdensome, especially in cases where product specifications and appearances change regularly. We will seek agreement for the LVD text to match the rest of the Directives in the package and for the requirement to be removed or retained as an option for those who wish to use it.

Pyrotechnics: sample testing by manufacturers:

It was thought by respondents that the manufacturer's obligation to carry out sample testing on products which they have supplied is unclear. The proposal talks of when "it is deemed appropriate with regard to the risks presented by a pyrotechnic article" to do so. Respondents have asked who has the responsibility to decide when sample testing is appropriate and on what legal basis.

Government response:

The Government understands that this is under further consideration, but it believes that the responsibility for making the decision would rest with the manufacturer.

Pyrotechnics: traceability and retention of records:

It is the view of manufacturers that the requirement for economic operators to keep records of transactions for ten years is excessive for pyrotechnic articles, specifically Category 1-4 and theatrical fireworks which are wholly consumed in use. Fireworks are generally sold and used within a relatively short period of time.

Government response:

The Government is in further discussion with respondents on this issue and the outcome of this will be taken into account during negotiations on the text.

Additional burdens on users of equipment covered by these proposals:

Some respondents were keen to clarify whether the proposals affected users of products covered by the proposals and to ensure that no additional burdens fell on them.

Government response:

Users of equipment covered by all nine Directives in the package are not generally affected by the changes, unless they are also manufacturers or importers. In response to specific questions on the Measuring Instruments Directive (MID), taxi drivers using meters covered by MID will not be affected.

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?

Concerns were expressed about the scope of this proposal. Currently, Trading Standards Services (TSSs) with notified body status can use a peer review system to ensure quality and consistency. Respondents thought that if the new requirements mean that all Local Authorities would have to obtain UKAS certificates, then this would have substantial cost implications and might have an adverse effect on the number of TSSs with notified body status.

Government response:

It is the Government's view that the NLF does not require all Notified Bodies to be assessed through the accreditation route. A member State can use alternative means which provides equivalence to accreditation. Any alternative means will be fully scrutinised and open to challenge by the Commission and other member States.

Question 8: Draft Impact Assessments (IAs)

The main comment on the IAs concerned the costs of the change of Directive numbers and transitional periods, this is discussed further below. In addition, a number of respondents thought that the IAs should also take into account costs brought about by the proposed

requirement in LVD for a colour image in the DoC, the proposed requirements for a single DoC and the revised requirements for retention of documentation.

Government response:

The IAs are “living documents” and will be revised as the proposals develop. We do need as much information on costs from stakeholders as they are able to share with us especially in regard to their concerns as stated above. We are very grateful for the cost information that has already been provided, particularly on the issue of changes of Directive number and transitional periods.

Change of Directive numbers & transitional periods:

This was a concern for a significant number of respondents, particularly manufacturers and Notified Bodies, who thought that the change to the Directive numbers as a result of the re-casts was unnecessary. They told us that such a change would mean that product documentation would have to be updated with the new numbers and this would take a lot of time and expense to little benefit. The issue was aggravated by the fact that the updates would have to take place for nine Directives at once. An extension to the transitional period and clarity on documentation was requested to ensure that documentation changes for as many products as possible can be carried out in normal updating cycles. However, some were sceptical about this as customers will often demand documentation with the up to date references ahead of when they were required by law.

Government response:

The change in Directive numbers is inevitable as the re-casts are effectively new Directives. The Government agrees there are things that need to be made clear, particularly with regard to when documentation must be changed. It is not within our gift to extend the transitional period for the UK implementing Regulations unilaterally. However, we will make the case to the European Commission that the guidance on when the required documentation has to be updated, and by when, should be made available at an early stage. We will also seek to agree that for products in serial product lines first placed on the market before entry into force of national implementing Regulations, manufacturers and other actors, including Notified Bodies can continue to use the current Directive numbers and references in documentation and certificates, at least for a reasonable transitional period. Finally, we will try to make the case for a longer transitional period to ensure documentation changes for as many products as possible can be carried out in normal updating cycles.

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?

Two respondents asked for the EMC Directive and LVD to be clarified with reference to the space and railway industries.

Government response:

It is the Government’s view that this would not be possible as it is beyond alignment.

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?

Enforcement bodies were in favour of enhanced traceability. Other respondents were concerned that this requirement was unclear and could contradict the requirements in the relevant harmonised standard (BSEN 15947) for fireworks in categories 1, 2 and 3. BSEN 15947 requires an identifying number linking the notified body and its customer together with information on the category of the firework. If additional labelling is required above that set out in the standard, manufacturers believe that this would create an unnecessary burden through the re-design of labels. In addition it was thought that the requirement would be difficult to meet due to the space constraints on labels.

Government response:

The Government is concerned that the Directive should not go beyond the current identification requirements in the harmonised standards. We are also keen to avoid additional burdens on economic operators where possible. We will seek clarification of the Commission's proposed text and try to agree amended text if necessary.

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?

Some respondents were of the opinion that there should be a definition of "authorised representative" in the Pyrotechnics Directive to ensure consistency with other Directives.

Government response:

It is the Government's view that the definition of an "authorised representative" is useful in other Directives, but not for the Pyrotechnics Directive due to the ephemeral nature of most pyrotechnic articles.

Question 12: 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 powers². Are these correctly applied or should they be reassessed in the light of the other changes ?

Respondents told us that they believed that reassessment would be necessary.

Government response:

We have noted the view of respondents and will pass it on to the European Commission.

² OJ L 55, 28.2.2011, p. 13.

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?

A number of differing views were expressed on the changes to role of Notified Bodies (NBs) in the EMC and Low Voltage Directives. Some are in favour of removing the (currently optional) role of Notified Bodies from the LVD, others oppose it.

Some respondents told us that in the light of the changes to LVD, the retention of a role for NBs under the EMC Directive looks like an anomaly, although there was a degree of acceptance that this merely reflects the current situation with EMC.

Government response:

On the role of NBs in the Low Voltage Directive, the Government supports the Commission's proposal to remove the role on the grounds that it would not prevent manufacturers from using an accredited test or inspection body to assess the compliance of their products if they wish to do so.

On the role of NBs in the EMC Directive, we are minded to agree with the Commission's proposal to support the voluntary use of NBs and to introduce Module B Type Examination as the basis of Conformity assessment.

Simple Pressure Vessels Directive: 2009/105/EC

Question 14: In Art 1.1 b) of the SPV proposal, the term "assemblies" has been changed for "components". Do you think that this is a significant change?

See responses set out under Question 15.

Question 15: Annex 1 of the SPV 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?

Several respondents believe that the changes may bring a change in meaning to the terms used in the current SPV Directive. The Commission does not appear to have justified these changes and even if no change is intended there is a risk that the proposed wording could lead to confusion.

Government response:

We believe that the proposals go beyond the scope of alignment and will seek agreement to retain the current wording.

In addition to the main issues outlined above, there were a significant number of changes suggested to the proposals to correct mistakes and omissions in the drafting. The Government has noted these and where we agree with them will seek corrections in forthcoming drafts.

Next steps

The Government will take forward some of the views expressed in the response to the consultation during the negotiation of the proposals as outlined in section 6 of this response. In some cases, we will seek clarification to the wording to ensure that the intention is clear.

Annex A: List of respondents

Association of Manufacturers of Domestic Appliances (AMDEA)

Atlas Copco

British Electrotechnical and Allied Manufacturers Association (BEAMA)

British Standards Institution (BSI)

CBI Explosives Industry Group

Council of Gas Detection & Environmental Monitoring (CoGDEM)

David Baker (individual respondent)

David Baker (consultant)

EADS Astrium Satellites

East of England Trading Standards Association

Engineering Equipment & Materials Users' Association (EEMUA)
Ian Moseley

Intellect UK

Intertek

John Green

Nokia UK

Society of Chief Officers of Trading Standards in Scotland

Telecom Policy Services Ltd

Trading Standards Institute

Tubelines Ltd

UK Weighing Federation

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