EVIDENCE BASE

Approach

1. The New Legislative Framework (NLF) Directives contain very similar provisions to existing legislation and as a result we believe the effect of new legislation is also likely to be the very similar in each sector. We have therefore considered seven of the nine NLF Directives under "overarching" headings but have been explicit where we believe that the legislation is likely to have an effect that is specific to individual Directives.

2. The remaining two Directives are being treated separately and are therefore subject to separate IAs. The Pyrotechnic Articles Directive (2013/29 EU) is being managed by the Department for Business, Innovation and Skills (RPC reference RPC14 – BIS – 2216(2)), and the Civil Explosives Directive (2014/28 EU) is subject to a separate IA which is being carried out by the Health and Safety Executive (HSE) because the proposed legislation contains provisions which fall outside the scope of the NLF.

3. Obtaining statistics and information relating to the impact of the Directives has been challenging. We have made assumptions based on the data which is available and included information that we have gathered from industry through informal consultation, meetings and internet searches and more recently the formal consultation.

Problem under consideration

4. In 2006 the European Commission conducted a review of the way that the internal market for goods was working. The Commission found that harmonised legislation was not working effectively across and within EU Member States. They identified three main problems including (i) the number of products that were on the EU market that did not comply with product safety legislation; (ii) the unsatisfactory performance of some Notified Bodies (NBs - the bodies which determine whether a product meets the essential requirements of the legislation) and (iii) difficulties in using and understanding the current legislation. The Commission proposed a Decision in an attempt to improve this.

5. The New Legislative Framework (NLF) which resulted is a common set of principles which aims to make legislation on the Single Market for Goods clearer, more consistent and more understandable. It was adopted as an EU Regulation and an EU Decision in July 2008. Subsequently an "Alignment Package" was introduced to align nine existing European Union Directives to the NLF. These are:

- *Civil Explosives 2014/28 EU*
- Simple Pressure Vessels 2014/29 EU
- Electromagnetic Compatibility 2014/30 EU
- Non Automatic Weighing Instruments 2014/31 EU

- Measuring Instruments 2014/32 EU
- Lifts and their Safety Components 2014/33 EU
- Equipment for Use in Explosive Atmospheres ("ATEX") 2014/34 EU
- Low Voltage 2014/35 EU
- *Pyrotechnic Articles 2013/29 EU*

6. The Pyrotechnic Articles Directive was adopted early and, therefore, a separate IA has already been prepared for its implementation so is excluded from this IA. The IA included some costs specific to pyrotechnic traceability requirements which are not included in the NLF. The Civil Explosives Directive is being considered separately as the transposing legislation is likely to contain new provisions which fall outside the NLF.

7. The remaining seven Directives are being considered in this single IA because we believe that the provisions contained within them are very similar and that the impact of transposing each piece of legislation will also be very similar across the relevant parts of industry.

8. We have added the Pressure Equipment Directive (PED – Directive 2014/68 EU) to the Impact Assessment (IA) since this Directive has also been aligned with the NLF, although to a slightly different timetable (the implementation deadline is 10 July 2016, instead of 20 April 2016) to the other Directives discussed. In addition to the alignment with the NLF the PED was also aligned with the latest Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (CLP – 1272/2008 EC), hence the different timescale to allow for negotiations on this aspect. The CLP alignment has now been implemented (this had to be done by 28 February 2015) and was subject to its own IA. Since the NLF alignment follows exactly the same pattern as the rest of the Directives, it was decided to include this aspect of the implementation under this IA to avoid unnecessary duplication of effort.

Obligations imposed through the Alignment Package

9. The list below sets out the obligations imposed through the Alignment Package, however some of these obligations are not new. The table below is more explicit about existing obligations that are confirmed in the Alignment Package and obligations that are entirely new.

Manufacturers

- To provide instructions and safety information with a product in a language easily understood by consumers and end-users
- To ensure that products bear the CE marking (which demonstrates conformity with the essential requirements of the Directive) and are accompanied by the required documents
- To ensure that the name and address of the manufacturer is indicated on the product or its packaging
- 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

Importers

- To keep a copy of the EU declaration of conformity and ensure that the technical documentation can be obtained when it is requested by authorities
- To check that the manufacturer outside the EU has applied the correct conformity assessment procedure
- To check that products bear the CE marking and are accompanied by the required documents
- To ensure that the name and address of both the manufacturer and importer is indicated on the products or the packaging
- To carry out sample testing and product monitoring as it applies to manufacturers

All Economic Operators (EOs): Manufacturers, Importers, Distributors, Lift Installers

- Introduction of traceability requirements: ensure traceability of products throughout the whole distribution chain. Manufacturers and importers must put their contact details on the product or, where this is not possible, on the packaging or an accompanying document.
- 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 (i.e. the procedure followed when a product is non-compliant and poses a risk): the new procedure ensures that the relevant enforcement authorities are informed about products which pose a risk and that similar action is taken against that product in all Member States

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

- Reinforcement of the notification requirements for NBs: To be authorised to carry out conformity assessment activities under the Directives, NBs must satisfy certain requirements. All NBs must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place for risk-based assessments which take due account of the size of the enterprise and the degree of the complexity of the product assessed. Subcontractors and subsidiaries, which carry out parts of the conformity assessment, must also fulfil the notification criteria.
- Revised notification process: Member States notifying an organisation as a NB must include information on the valuation of competence of that body. Other Member States may object to the notification within a certain period. Where competence is demonstrated by an accreditation certificate, a facilitated procedure applies. Where Member States have not used accreditation to evaluate the body's competence, documentary evidence must be provided and the objection period is longer (at 2 months).

- Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of NBs): Specific requirements and obligations for notifying authorities are introduced according to which they must be organised and operated so as to safeguard objectivity, impartiality and competence in carrying out their activity. Notifying authorities must de-notify bodies which no longer meet the notification requirements or fail to fulfil their obligations
- Information and other obligations for NBs: NBs must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other NBs about negative conformity assessment results. They must perform conformity assessment in a proportionate manner taking due account of the size of an enterprise, the structure of a sector, the complexity of the product technology etc.

Measures intended to ensure more consistency among the Directives:

- Alignment of commonly used definitions and terminology: Definitions of common terms like “manufacturer”, “importer”, “placing on the market” are introduced into the Directive concerned. Existing conflicting definitions are removed.
- 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.

Rationale for intervention

10. The purpose of the alignment is to make products in the EU safer, and to make the Single Market function more effectively, by making the relevant legislation easier for users to understand and apply. In order to meet our EU law obligations the Directive must be transposed into national law by April 2016.

11. We propose to implement the requirements of the Directives pertaining to this IA by revoking and replacing:

- The Simple Pressure Vessels (Safety) Regulations 1991, as amended in 1994
- Electromagnetic Compatibility Regulations 2006
- Non-automatic Weighing Instruments Regulations 2000 (as amended)
- The Measuring Instruments Regulations (there are 15 individual instrument regulations plus amendment regulations which will be revoked and replaced by one omnibus regulation covering all instrument types).
- The Lifts Regulations 1997
- The Equipment and Protective Systems Intended for Use in Explosive Atmospheres Regulations 1996, as amended in 2001 and 2005
- Electrical Equipment (Safety) Regulations 1994

Policy Objective

12. The objective is to transpose the requirement of the Directives into UK law. This will (i) ensure that the safety and economic benefits of clearer legislation, and improved traceability, reach UK consumers and workers; and (ii) ensure that products first placed on the market are compliant.

Description of options

13. We considered two possible options for each Directive. It is not possible to do nothing as the UK has treaty obligations to implement the Directives; not transposing them would expose the UK to a high risk of infraction.

Option 1 – make legislation to implement the Directives – **PREFERRED**

14. We propose to implement the legislation by revoking and replacing the existing legislation. This option would ensure that the UK regulations reflect the updated obligations and requirements.

Option 2 – non-regulatory approach

15. We considered a non-legislative approach and rejected it. This is because it would not meet the UK's EU law obligations to implement the Directives by binding measures of national law which provide for legal certainty.

Monetised and non-monetised costs and benefits of options

Option 1 – make legislation to implement the Directives

Overarching benefits

Table: Short Summary of Key Benefits and Estimated Impact:

Change	**Is this a new requirement?**	**Bodies affected**	**Estimated level of awareness of the change (High/Medium/Low)**	**Description of the benefit**
Retention of information about other EOs in the supply chain – need to keep information for 10 years (15 in the case of lifts)	Partially. EOs are already required to retain some information however the requirement will be broadened. In some cases the products concerned will have a life span of less than 10 years.	EOs Market Surveillance Authorities	Medium. Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	This should facilitate a more effective Market Surveillance regime as market surveillance authorities will have greater access to information about products. This should lead to a greater proportion of safe products on the market. It should be noted, however, that where products have a life span of less than 10 years there is potential that EOs will be expected to retain information about

				products which are no longer on the market.
Reinforcement of notification requirements and exchange of information	Partially. NBs are already required to exchange information, however the obligation has been widened and so exchanges will need to be more frequent.	NBs	Medium. There is high awareness among UK NBs of the new Directives, however some may be less familiar with the detail than others.	Facilitated exchanges between NBs should make it easier to find information about conformity assessments and conformity assessed products. This should lead to a greater proportion of safe products on the market and may facilitate more effective competition in the Single Market.
Traceability requirements	Partially Manufacturers and importers are already obliged to include identifying information on products but the amount required will increase	Manufacturers Importers Market Surveillance Authority	Medium. Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	Market Surveillance Authorities will find it easier to trace a product's origins and this will help them to determine whether or not a product is safe. It might also enable market surveillance activity to be more targeted and proportionate.
Post marketing obligations (sample testing, keeping a register of complaints etc.)	Partially. Some bodies already have these systems in place however those who do not will need to establish them.	Manufacturers Importers Market Surveillance Authorities	Medium. Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	Market Surveillance Authorities will find it easier to trace a product's origins and this will help them to determine whether or not a product is safe. This will also assist with post-market surveillance

Harmonised Legislative Environment

16. The legislative environment in the EU is complex and inconsistent, with products often being regulated by several legal instruments with different objectives. They therefore often use different terminology. For example under the current Measuring Instruments Directive the term "manufacturer" means a "natural or legal person responsible for the conformity of the measuring instrument with this Directive with a view to either placing it on the market under his own name and/or putting it into use for his own purposes". Under the Lifts Directive "the manufacturer of the safety components" shall mean the natural or legal person who takes responsibility for the design and manufacture of the safety components and who affixes the CE marking and draws up the EU declaration of conformity", and under SPV "manufacturer" means any natural or legal person who manufactures a vessel or has a vessel designed or manufactured and markets that vessel under his name or trade mark".

17. Manufacturers must currently comply with all of these requirements which means that they incur additional costs. The introduction of a set of common requirements will make it easier for all EOs to understand their obligations as these will not vary between Directives. Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market and level the playing field between manufacturers. This will have positive implications for competition.

Increased responsibility of importers

18. Consumers will be better protected, as importers will have an increased role in ensuring that only safe products are placed on the market. Currently some importers rely on a general statement from the manufacturer that they have complied with their obligations. In future, importers will have a clearer list of the things that they need to check (e.g. that the product has been conformity assessed, bears the CE marking and is accompanied by the required documents) and will have some additional obligations (e.g. indicating their name and contact details on the product). This will make it easier for importers to know what they need to do and easier for market surveillance authorities to check compliance.

Declarations of Conformity

19. Additional requirements in the Declaration of Conformity will lead to more effective enforcement, because they require an economic operator to provide more information about the product, which should in turn facilitate more effective market surveillance of products.

Notification process

20. There could be marginal benefits to organisations wishing to become NBs as a result of a clearer explanation of the notification process that they will need to follow. This could, for example, decrease the administrative costs involved in the notification process.

Enforcement

21. Some British Trading Standards departments have indicated they do not receive a large number of complaints about unsafe or potentially unsafe products from consumers (though it should be borne in mind that consumers may not approach them directly and in some cases not complain at all) and they do not therefore envisage much in the way of financial benefit accruing to consumers from the proposed amendment, although this should nevertheless reduce such complaints. This is because fewer non-compliant products will be available on the market and because it will be easier for enforcers to identify and take action in respect of these products. Customers will therefore be less likely to encounter these products, which should reduce the number of complaints made.

22. Industry stakeholders also anticipated the changes being beneficial by levelling the playing field between manufacturers (and especially with those importing from outside the EU) and between manufacturers and retailers of own-brand goods who would now also be covered by the legislation.

Increased business and financial savings for NBs

23. There may be financial savings and additional business for some NBs in the short term. Where products are certified by conformity assessment bodies, the requirements on those bodies will increase. This may generate a greater income for accreditation bodies in the short term, since there will be a significant number of new inspections/notifications to process. This gain is likely to be offset by the loss to companies of having to pay the fees.

Traceability

24. 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, and remove dangerous goods quickly and efficiently from the market.

25. There may be some financial savings in enforcement costs; improved traceability requirements and increased co-operation between NBs for articles placed on the market may reduce the amount of time that it takes to enforce the legislation.

Specific benefits:

Measuring Instruments Directive and Non-Automatic Weighing Instruments Directive

26. Implementation in the field of measuring instruments will cause a significant improvement in the verification sector by improving the standard of 3rd party assessment from the level which it is currently at. The increased scrutiny for the notification process of conformity assessment bodies will inhibit other member state national authorities appointing NBs without undergoing due process. This is important for the UK as non-accredited NBs are already subject to a process of validation which is equivalent to the system used by accredited bodies but which does not have a cost associated with this.

Overarching Costs

Retention of information

27. There will be a duty for all EOs to keep information for ten years as to who supplied them with a product and who they have supplied a product to. Some of the products may have a lifespan of less than ten years. The additional data collection and storage cost is expected to be marginal for many EOs given that much of it will be now stored electronically and many firms will

already keep some records. There was nothing in the formal consultation responses to contradict this assumption.

Change of Directive number

28. A new Directive number might lead to minor logistical difficulties and costs being incurred for manufacturers and NBs necessitating the re-drafting and re-issue of documents and manuals to include the revised number. Those involved in writing standards will also be involved in discussions on how the standards should cross-refer to legislation. There will be a transitional period before these requirements will come into force hence any alterations could be incorporated more broadly into periodic updating. While we would not expect the additional cost associated with the redrafting and reissue to be significant some stakeholders have raised this as a concern. No further evidence was provided on this point as part of the formal consultation.

Notification process

29. NBs for the industries concerned could be affected due to reinforcement of the notification requirements and information obligations – strengthened obligations on information sharing among NBs would lead to some increase in on-going 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. NBs that we have spoken to already have not suggested that this will impose significant costs.

Familiarisation costs

30. Enforcers, industry and government will need to ensure that importers, manufacturers and distributors are aware of changes to legislation (for example in relation to withdrawal/recall, and the associated procedures) and this could lead to some one-off costs. No further information was supplied on this point as part of the formal consultation.

Table: Summary of key costs and estimated impact

Change	**Is this a new requirement?**	**Bodies affected**	**Estimated level of awareness of the change (High/Medium/Low)**	**Description of the cost**
Retention of information – need to keep information for 10 years (15 in the case of lifts)	Partially. EOs are already required to retain some information however the requirement will broadened. In some cases the products concerned will have a life span of less than 10	EOs Market Surveillance Authorities	Medium. Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	The costs with collecting and retaining additional data is expected to be marginal.

	years.			
Change of Directive number	Yes	All	High. The majority of bodies who this will affect have been aware of the forthcoming changes for some time, although there will be some bodies who are unaware of the change.	There will be low one-off costs in changing the Directive number on official documents.
Reinforcement of notification requirements and exchange of information	Partially. NBs are already required to exchange information, however the obligation has been widened and so exchanges will need to be more frequent.	NBs	Medium. There is high awareness among UK NBs of the new Directives, however some may be less familiar with the detail than others.	We do not expect this to be a significant cost. Exchanges between NBs already occur, although these will increase.
Traceability requirements	Partially Manufacturers and importers are already obliged to include identifying information on products but the amount required will increase	Manufacturers Importers Market Surveillance Authority	Medium. Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	We anticipate that the one-off costs of including this information might be high, however the cost in the longer term will be lower.
Post marketing obligations (sample testing, keeping a register of complaints etc.)	Partially. Some bodies already have these systems in place however those who don't will need to establish them.	Manufacturers Importers Market Surveillance Authorities	Medium. Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	42% of EOs and 23% of SMEs attribute no/no significant cost increase. 30% of EOs and 18% SMEs attribute a significant cost increase[1].

Specific Costs

Measuring Instruments Directive and Non-Automatic Weighing Instruments Directive

28. As part of the control of measuring instruments on the UK market provisions are included for in-service control and relate to the removal of individual instruments from the market place and the potential re-qualification of the same. The provisions complement the safe guard clause of the Directive. The provisions are identical to those already in existence in the current legislation and therefore there are no additional costs.

[1] European Commission Impact Assessment

Lifts Directive

29. The Lifts and Escalators Industry Association (LEIA) have advised that a change in documentation may present a significant logistical challenge when new legislation comes in to force – Lift projects can typically take from 6 months to 3 years from negotiation of the contract to putting in to service and there may be costs associated with the transfer of paperwork from the existing Directive to the new Directive over this period. However LEIA and the NBs for Lifts are well aware of the proposed legislative changes and have prepared for them, so the impact of this change should be limited.

30. There is one technical change in the new Directive concerned with the redefinition of safety components to prevent uncontrolled movement. It is currently unclear how this should be interpreted; costs may be a consideration if manufacturers will need to resubmit their products for EU Type Examination, however this cannot be quantified at the present time.

Comment

31. Many of the changes associated with the new Directives present both costs and benefits. For example new traceability requirements and the need to retain documents for 10 years (15 in the case of lifts) will inevitably lead to increased costs for specifically for manufacturers and also for other EOs in the supply chain. However this should also lead to a more effective market surveillance regime, with market surveillance authorities being able to more efficiently check products. This should in turn lead to a greater proportion of safe products on the market. There was general agreement on this point in the responses to the formal consultation.

Option 2 – non-regulatory approach

Overarching benefits

32. Nil.

Overarching costs

33. This option would ignore the legal requirement for Member States to implement as set out in the Directives.

Risks and assumptions

34. We have assumed that industry is already keeping a certain amount of the new data required, e.g. site of manufacture of imported of articles, and that they have efficient data retrieval systems; BIS has been speaking to Industry routinely about the alignment package for a number of years and so we expect the majority of them to have prepared for the changes. However this is less likely to be the case for small or micro businesses so costs could be more than anticipated. No further information on this point was raised during the formal consultation process even though we sought specific evidence on

this point. There was general support for the evidence and assumptions used in the impact assessment.

Affected groups and size of industry

Overarching

35. The Directives extend responsibilities to include all EOs in the supply chain.

36. NBs offer certification and approval services to their clients, often across a range of Directives. They also vary widely in terms of their size. For example, Lift Cert is a NB for the Lifts Directive and also for the Machinery Directive (the latter is not covered by this IA) and is a small, family-run business. However, another NB under the Lifts Directive is Bureau Veritas; Bureau Veritas covers multiple sectors across many countries. A Notified Body's capacity to respond to the changes presented by the new Directives can therefore vary widely.

37. NBs will be affected due to the reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations. Approximately 75 NBs will be affected by the 7 Directives in question, of which several are NBs for multiple Directives.

38. Enforcement Agencies will need updated training on the revised requirements.

Pressure Equipment and Simple Pressure Vessels

39. Simple Pressure Vessels are included in the wider pressure equipment sector (most covered by the Pressure Equipment Directive) Gross Value Added (GVA), which, for the wider pressure equipment sector is approximately £1.7 billion, with a turnover of £54 billion and 653 companies, employing approximately 31,000 people[2]. The sector comprises mostly of SMEs, with a few larger multi-nationals that make SPV equipment as part of a wider product range.

NAWI (Non-automatic Weighing Instruments)

40. NAWIs account for €2.5 billion in market output in the EU. 95% of the industry structure is made up of SMEs (Commission IA, 2011).

Measuring Instruments

41. Measuring instruments account for approximately £3.6 billion in GVA and £7.6 billion in turnover, with approximately 2,000 companies and 53,000 employees (ABI, 2013 data).

[2] ABI (ONS Annual Business Inquiry)

Lifts

42. It is estimated by an industry association that the industry employs approximately 10,500 persons in total. The value of the sector during 2009 was estimated at £332 million GVA. They also estimate that the majority of companies are medium sized. Figures provided by one respondent to the formal consultation suggested that there are around 200 businesses operating within the sector.

ATEX

43. It is not possible to estimate the size of this sector as it isn't captured in official data – it will, for example, cover the adaptation of existing machinery for use in explosive atmospheres rather than the original machinery. The EU IA for the NLF estimates the turnover – if apportioned on the basis of the UK population a s a proportion of EU population (12%) turnover in the UK could be around £0.3 billion. It is estimated in the EU IA that approximately 90% of the companies in this sector are SMEs.

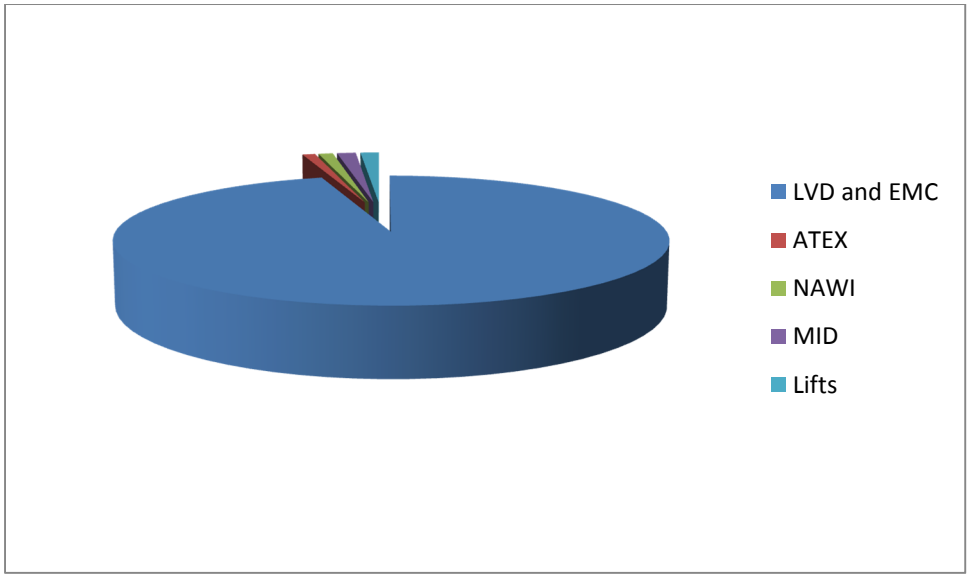
Low Voltage and EMC

44. The extension of responsibilities to include all EOs in the supply chain 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.

45. The proposal omits the function of NBs in the conformity assessment process entirely. Currently NBs are infrequently used so the change is unlikely to have a significant impact on them. There will be loss of income to some extent; while we sought further information regarding this through the consultation additional information was not forthcoming. As the use of NBs was very small we conclude that any loss of income is of very low significance.

46. The LVD sector (+ EMC) equates to approximately £13.6 billion GVA and £31 billion in turnover. These are the largest sectors of the other 6 Directives. There are approximately 9000 enterprises employing 20,000 people (ABI, 20013 data).

<u>Chart: Proportion of Industry output in the EU (EU Market Output – available data)</u>



Direct costs to business and One In, Two Out

47. All the proposed changes to UK legislation flow directly from changes to the eight EU directives outlined above and as such the measures are not considered to be part of the One In, Two Out regime as set out paragraph 1.9.9.ii of the Better Regulation Framework. The transposition of the directives does not include gold plating; we have used copy-out where possible. The UK has exercised derogations to retain pre-existing harmonised standards however there are not higher than the minimum outlined by the EU legislation. We consider this approach is justified on the grounds of public order and health and safety; there is nothing to suggest that these derogations have reduced competition in the UK market for these products and the risk of reduced competition is offset by the increased health and safety benefits.

48. Many of the direct costs to industry will arise from new labelling and data retention requirements. Rather than seeking to itemise these separately for each potential costs element, we have used feedback from industry gathered in a number of meetings and in correspondence since the initial Decision on the Alignment Package was issued to give an indication of costs and impact according to different elements of the supply chain. Much of this information is common across the Directives but where we have specific information this is made clear below.

Overarching

49. New traceability requirements could increase operating costs and/or administrative burdens 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. The 2011 EU IA survey results suggested that 55% of general EOs believe that this will result in a moderate impact on costs, and that 1 – 5% expect a significant costs increase. These will mostly be one-off costs (the data retention costs and some traceability requirements will be on-going).

50. Post marketing obligations (e.g. sample testing, keeping register of complains and defective products) will, if appropriate, need to be established if not already in place.

Table: Sector Definitions and Industry Size

Directive	**Examples of products**	**Size of industry (EU market output)**[3]	**Size of industry (UK) (GVA)**	***Industry Structure in UK***	**No. UK Businesses**[4]	**No. UK employees**[5]	**No. NBs (EU)**[6]	**No. of NBs (UK)**
LVD and EMC	LVD:Electric welding and soldering tools, computers, lighting equipment and lamps EMC: electric domestic appliances, television and radio receivers	€235.59 billion	£13.6 billion[7]	*A few large corporations producing a wide range of electrical equipment, and many small companies specialised in niche markets*	9000	220000	148[8] (LVD) 131 (EMC)	18 (LVD) 26 (EMC)
ATEX	Mechanical, electrical and telecommunication equipment, protective systems and devices, to be	€2.2 billion	£0.3 billion (estimate)[9]	*A large number of SME and micro enterprises, around 90% of which are based in France, Germany and the*	Not obtainable	Not obtainable	55	7

[3] EU New Legislative Framework (NLF) Alignment Package Impact Assessment, 2011
[4] ABI, 2009
[5] ABI, 2009
[6] EU New Legislative Framework (NLF) Alignment Package Impact Assessment, 2011
[7] ABI, 2013
[8] Under the new LVD Directive there will be no NBs in the UK
[9] ABI, 2009

	used in potentially explosive atmospheres			*UK*				
NAWI	Measuring instruments serving to determine the mass of a body and requiring the intervention of an operator during weighing	€2.5 billion		*Small companies*			270	57
MID	Water meters, gas meters, weighing machines, taximeters	€3.25 billion	£3.6 billion [10]	*Around 20 – 25% of measuring instruments in the EU27 are imported*	2000	53000	140	37
Lifts	Lifts permanently serving buildings and constructions intended for the transport of persons, persons and goods, or goods alone if the car is accessible as well as safety components for use in such lifts	€3.17 billion	£0.332 billion	*Four multinational lifts companies and many specialised small companies Which design and install new lifts and produce safety components for these lifts*	Approx. 200 (industry estimate)	10500	192	6
SPV	Boilers, generators	Not availabl	£1.7 billion[11]	*A substantial number of SMEs*	677[12]	27000[13]	95	8

[10] ABI,2013

[11] ABI, 2013

		e		*involved in production*				

[12] ABI, 2013

[13] ABI, 2013

51. 42% of general EOs and 23% of SMEs attribute no/no significant cost increase to these elements whilst 30% of EOs and 18% of SME a significant increase. These will mostly be one-off costs[14].

52. If 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.[15]

53. A new Directive number might lead to costs being incurred for manufacturers and NBs necessitating the re-drafting and re-issue of documents to include the revised number. These costs will be one-off although for some companies a large number of documents might need to be updated. This point was not raised as a particular issue in the responses to the consultation.

54. We expect that strengthened obligations on information sharing among NBs (e.g. on withdrawn certificates etc.) will lead to some increase in on-going 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.

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

56. The formal consultation, discussions with industry bodies and individual NBs have not to date provided any firm evidence in relation to these likely administrative costs. We have therefore attempted to illustrate the potential administrative costs to business following the approach used in the IA for Pyrotechnic Articles which assumed a certain number of additional administrative inputs per firm – both one-off and on an ongoing basis. We have however halved the number of additional hours assumed to be worked compared to the Pyrotechnics IA to account for the additional traceability elements which are included in the Pyrotechnics Directive and which are not present in the remaining directives. We have also provided figures in the covering sheets for both a high scenario (the ongoing cost of 200 additional admin hours) and a low cost scenario (the ongoing cost of 50 additional admin hours). Under these assumptions the best estimate total annual cost to firms is £16.2m with a one-off cost of £6.5m (annual cost £8.1m in the low scenario and £32.3m in the high scenario). These assumptions were generally supported by the responses to the consultation process.

	Hours	**Wage cost**	**Uplift**	**cost to employer**	**Cost/firm**
One off cost	40	11.46	0.198	13.73	549
Ongoing cost	100	11.46	0.19	13.753	1,373

[14] European Commission Impact Assessment 2011

[15] European Commission Impact Assessment 2011

	No. of firms	**One-off cost**	**On-going**	**Total £**	**Total £M**
Pressure Equipment/Simple Pressure Vehicles (figures are for the total pressure equipment sector)	677	371783.49	929458.72	1301242.20	1.30
NAWI (covered by Measuring Instruments)				0.00	0.00
Measuring Instruments	2100	1153242.72	2883106.80	4036349.52	4.04
Lifts	200 (trade body estimate)	109832.64	274581.60	384414.24	0.38
ATEX (not included – the range of machinery adapted this directive is difficult to identify)		0.00		0.00	0.00
Low Voltage & EMC	9000	4942468.80	12356172.00	17298640.80	17.30
Total £	11935	6577327.65	16443319.12	23020646.76	
Total £million		6.58	16.44	23.02	23.02

We tested these assumptions as part of the formal consultation process (which ran for 8 weeks from 4 Aug 2015). We received only 27 responses from across the sectors affected of which 14 were from businesses or business representative bodies and most either agreed with the IA assumptions or did not have any better information to suggest any different assessment of likely costs.

Small and Micro Business Assessment

We do not have specific information on the likely costs for small firms operating within the affected sectors but proportionately these are likely be greater than for larger firms. The EU considered the impacts on small firms in their original impact assessment but did not conclude that these were sufficiently significant to warrant any SME specific measures. In particular, they found that SMEs were equally likely to be affected by the problems of non-compliance, Notified Bodies of variable quality and difficulties understanding and applying the current legislation.

It is also the case that excluding or partially excluding small and micro businesses would undermine the intended impacts of the proposed changes as it might mean small businesses placing onto the market unsafe products which would undermine consumer confidence in the regime and might be seen as providing unfair competitive advantages to smaller businesses.

A longer transition period and/or specific guidance for smaller firms are not considered necessary as firms within the affected sectors are very familiar with managing regulatory change and the changes for most businesses will be relatively minor and represent existing good practice for many. The consultation responses and wider stakeholder engagement have not suggested that small or micro businesses will have any difficulties in complying with these amendments. In addition, there has been extensive engagement with sector and trade associations over a number of years about the nature and detail of the alignment changes and these have in turn ensured their members are aware of the anticipated changes, providing additional guidance where necessary.

Low Voltage Directive

57. All 20 NBs will cease to be authorised in respect of the LVD as they will not have a function. It should be noted that there will not be a loss of current revenue to these bodies. This will be the case across the EU. As the NBs are usually used as test houses rather than NBs (and which test a large number of other products) any loss would be down to loss of prestige by not being a NB.

Direct impacts on NBs

58. There could be marginal benefits to organisations wishing to become NBs from a clearer indication of the notification process. NBs that wish to become accredited to make conformity assessments under the new Directives will be charged a fee by the UK Accreditation Service (UKAS). There are 47 NBs, not including those which provide services under LVD (which will no longer require NBs), NAWI and MID (who NBs are not accredited and are unlikely to be able to apply for this status).

59. If we assume that assessment under the new Directives is a simple process (as we anticipate, given that this is a simplification of legislation rather than legislation introducing many new requirements), an indicative cost to NBs might be calculated as follows (figures obtained from the United Kingdom Accreditation Service (UKAS)):

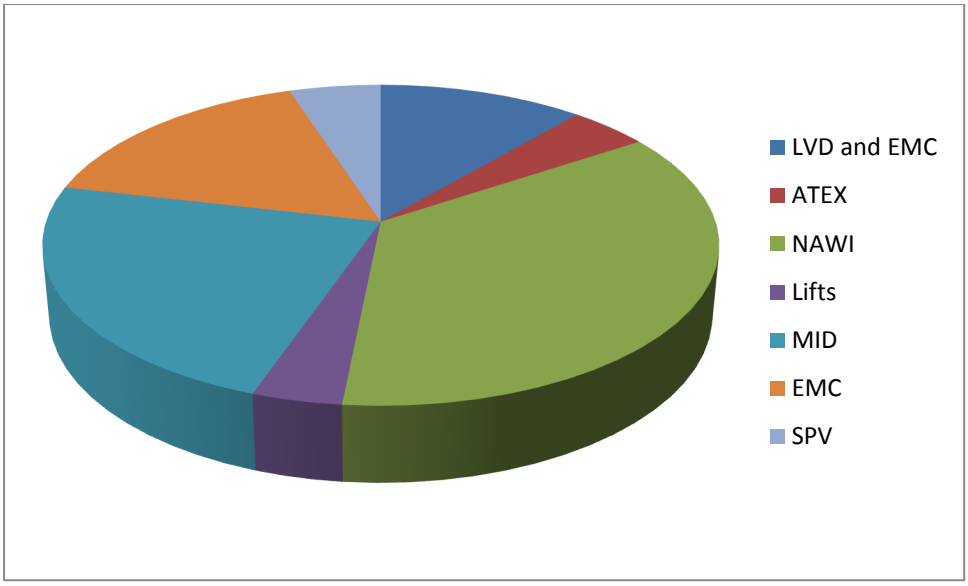
- Head Office visit = 2 days (1 day x 2 people) x £820 (standard assessment day rate) = £1640
- Witnessed Assessment and cost of follow up = 1 day x £820 (standard assessment day rate) = £820
- Total = £2460 per Notified Body per Directive x 47 NBs = £115,620

60. This figure does not include the cost of accreditation which would not be an extraordinary cost. The figure above is indicative as the number of Head Office visits, assessments and follow up work may vary. Bodies which wish to become accredited for the first time may be charged additional and optional fees for pre-assessment documentation reviews, at approximately £1080.

61. NBs may elect to recuperate the cost of accreditation through their charges to business but as the evidence on this point is not strong we have only included this small additional cost in the high cost scenario.

62. The harmonisation measures could lead to a significant increase in costs to Local Authority NBs, which currently benefit from a peer audit system which is carried out at little cost by Local Authorities. Should this system be declared as being out of the spirit of the legislation there would be a significant (and possibly fatal) change to the provision of services across the country. This impact will be felt more greatly by bodies which currently use this system for work on the Measuring Instruments Directive and the Non-Automatic Weighing Instruments Directive.

Chart: Proportion of NBs in the UK after implementation



Following transposition there will be no NBs for LVD

Total net present value and EANCB

63. Using the assumptions and figures set out above gives a total net present value in 2014 prices and 2015 present value of £148.09 million over the ten year period considered and an equivalent annual net cost to business (EANCB) of £16.93 million. This figure is comprised solely of costs as we have not been able to quantify any benefits from the proposed changes although stakeholders replying to the consultation expected that the changes would be beneficial for the reasons set out above.

Direct benefits to business

64. There could be marginal benefits to organisations wishing to become NBs because the notification process will be easier to understand. Additionally some benefits are expected from clarifications and harmonisation of definitions across Member States, though it is not possible to quantify these.

Overarching

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

66. 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.

67. We expect that there will be some benefit from clarification and harmonisation of definitions and duties for business across Member States.

Impact on enforcement bodies

Overarching

68. The traceability obligations of the Directives will facilitate the identification of EOs having marketed non-compliant products. This may reduce the cost of investigations for enforcement bodies. This point of view was supported by responses to the consultation process.

69. Clearer duties on operators throughout the supply chain may also bring some minor cost benefits in that enforcement agencies will be able to target more directly those infringing the requirements.

70. Enforcement will be assisted by the obligation in most cases to use authorised NBs (NBs) to demonstrate compliance. Existing manufacturers 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.

71. There would be a moderate (temporary) increase in administrative burdens arising from the need to request new notifications and to produce updated evidence to show compliance with the new requirements (e.g. accreditation and/or other certificates showing professional qualifications). Accreditation is not mandatory but many NBs are already accredited.

72. 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 strengthening of NB requirements is not expected to lead to any

additional operating costs and/or administrative burdens on NBs that act in accordance with recognised professional standards.

73. 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.

Low Voltage

74. One-off training costs and updating costs to enforcement agencies – estimated by the Health and Safety Executive (HSE) to be approximately £5,000. This is likely to be conducted as part of a routine update.

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

Wider impacts

Overarching

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

77. Social impacts: benefit to the 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).

78. Environmental impacts: reduction in the risk of environmentally unfriendly goods and prevention of accidents leading to environmental risks.

Formal Consultation and Other Evidence Gathering

79. As part of the call for evidence during our consultation we sought more detailed information on likely business costs of the proposed changes. In particular we asked for evidence of costs for the new requirement for EOs to keep 10 year data (15 year data for lifts) on who they have supplied products to and who has supplied them with products and, for manufacturers and importers, the site of manufacture. We also asked about any costs incurred from the new requirements on labelling with product, batch and serial number and the new requirements in relation to post-marketing obligations. However, we received only a relatively small number of responses to the formal consultation (27) and whilst a handful of these provided some estimate of costs (either financial or in terms of time) there was insufficient detail provided to incorporate the responses.

80. When asked about the likely benefits of the changes 12 of those responding (out of 18) agreed that there were likely to be benefits in terms of improved enforcement and traceability and greater clarity around the obligations imposed by the regulations. Those who did not anticipate benefits from the changes were mainly concerned about the ability of the enforcement regime to deliver such impacts.

81. We also discussed the proposed changes and sought evidence during a number of routinely held Industry meetings during the consultation period to elicit further information however no strong views were expressed.

82. We also held direct discussions with a range of trade associations and notified bodies about the likely costs they or their members might face but for the most part they confirmed the view that any additional costs were likely to be relatively minor and would therefore be largely absorbed by notified bodies.

Summary and preferred option

83. In summary we recommend Option 1: to make legislation to implement the Directives. This should help to make products safer by making the relevant legislation easier for users to understand and apply. It should make it easier to trace products throughout the supply chain and thereby improve market surveillance.

84. We anticipate that the overall costs and benefits will be modest given that this is an alignment of existing legislation rather than the introduction of many new requirements; the benefits are harder to quantify than the costs which are in part one-off costs arising from the need to adapt to the new requirements. However there is cautious optimism in business that the Directives will succeed in achieving the long term aim of improving the internal market in products through more effective market surveillance, better regulation of NBs and more effective legislative harmonisation.

85. We would implement by bringing in secondary legislation to revoke and replace the existing legislation listed above.

86. This would bring the clarity of a fresh set of easy to understand regulations rather than introducing confusing amendments into the existing legislation. We believe that Industry is already aware of the requirements of the legislation and so should be prepared for implementation by 2016. Copy out will be used in transposing the Directives where possible, however it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty. Implementation should help to progress the long term aim of improving the internal market in products through more effective market surveillance, better regulation of NBs and more effective legislative harmonisation.