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The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017 – S.R. 2017 No. 90

Impact Assessment

An Impact Assessment (IA) is a tool, which informs policy decisions. All NI Government Departments must comply with the impact assessment process when considering any new, or amendments to existing, policy proposals. Where regulations or alternative measures are introduced an IA should be used to make informed decisions. The IA is an assessment of the impact of policy options in terms of the costs, benefits and risks of the proposal. New regulations should only be introduced when other alternatives have first been considered and rejected and where the benefits justify the costs.

The IA process is not specific to the UK Civil Service or the NI Civil Service – many countries use a similar analysis to assess proposed regulations and large organisations appraise their investment decisions in similar ways too.

Attached please find the final IA in respect of the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017.

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THE EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS (NORTHERN IRELAND) 2017

NOTE ON COSTS AND BENEFITS

1. I declare that:

   a. the purpose of the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017 ("the Northern Ireland Regulations") is to replicate, for Northern Ireland, the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (S.I. 2016/1107) ("the Great Britain Regulations"); and

   b. I have seen an impact assessment relating to the costs and benefits in respect of the Northern Ireland Regulations.

2. There is no impact on charities, social economy enterprises or voluntary bodies.

3. A copy of the impact assessment relating to the Northern Ireland Regulations is appended to this Note at Annex A.

Colin Jack
Department for the Economy

15 June 2017

IMPACT ASSESSMENT FOR THE EQUIPMENT AND PROTECTIVE SYTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS (NORTHERN IRELAND) 2017

1. This Impact Assessment (IA) draws on the contents of the IA published with the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (S.I. 2016/1107) made by the Department for Business, Energy and Industrial Strategy, whose assistance is gratefully acknowledged.

2. That Great Britain IA[1] considers seven of the nine Directives under "overarching" headings. Much of this assessment, including the summaries of benefits and costs, refers to the overarching consideration of the effects of implementing these Directives in the alignment package, but HSENI is content that all of this consideration is directly applicable to the transposition of the ATEX Directive as part of that package.

Problem under consideration

3. 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.

4. 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
   - Pressure Equipment 2014/68/EU.

[1] http://www.legislation.gov.uk/ukia/2016/222/pdfs/ukia_20160222_en.pdf and http://www.legislation.gov.uk/uksi/2016/1107/pdfs/uksiod_20161107_en.pdf

5. Of the nine Directives, five are of interest to HSENI – simple pressure vessels, lifts and their safety components, ATEX, low voltage and pressure equipment. However, current legislation relating to four of the five is made on a UK-wide basis, and the new implementing Regulations will also be made on that basis.

6. In the case of the ATEX Directive, current legislation is made separately by Great Britain and Northern Ireland and the new implementing Regulations will also be made separately.

Obligations imposed through the whole Alignment Package

7. The details below set 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

- 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 Notified Bodies (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

8. 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 EU law obligations the Directive was required to be transposed into national law by 20 April 2016.

9. This assessment relates solely to implementation of the ATEX Directive. We will transpose the requirements of that Directive by revoking and replacing the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996.

Policy Objective

10. The objective is to transpose the requirements of the ATEX Directive into Northern Ireland law. This will (i) ensure that the safety and economic benefits of clearer legislation, and improved traceability, reach NI consumers and workers; and (ii) ensure that products first placed on the market are compliant.

Description of options

11. We considered two possible options. 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 Directive – **PREFERRED**

12. We propose to implement the legislation by revoking and replacing the existing Regulations. This option would ensure that the Northern Ireland Regulations reflect the updated obligations and requirements.

Option 2 – non-regulatory approach

13. We considered a non-legislative approach and rejected it. This is because it would not meet the UK's EU law obligations to implement 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 Directive

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	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 Directive, 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

14. 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. 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

15. 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

16. 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

17. 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

18. 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, it is likely that customers will be less likely to encounter products which are unsafe or potentially unsafe. This should reduce the number of complaints made to enforcers.

19. There are also indications that industry stakeholders anticipate 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

20. 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

21. 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.

22. 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.

Costs

Retention of information

23. There will be a duty for all EOs to keep for 10 years information in relation to who supplied them with a product and to whom they have supplied a product. 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 were no responses to the formal consultation to contradict this assumption.

Change of Directive number

24. 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 operation hence any alterations could be incorporated more broadly into periodic updating. We do not expect the additional cost associated with the redrafting and reissue to be significant. No further evidence was provided on this point in response to the formal consultation exercise.

Notification process

25. NBs 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. To date we have no indication that this will impose significant costs.

Familiarisation costs

26. 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 evidence was provided on this point in response to the formal consultation exercise.

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	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 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.	The cost with collecting and retaining additional data is expected to be marginal.
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 Directive, 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	Manufacturers Importers	Medium. Trade Associations, for	We anticipate that the one-off costs of

	and importers are already obliged to include identifying information on products but the amount required will increase	Market Surveillance Authority	example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	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[2].

Comment

27. Many of the changes associated with the new Directive present both costs and benefits. For example, new traceability requirements and the need to retain documents for 10 years 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. No additional information was received in response to the formal consultation to contradict this assumption.

Option 2 – non-regulatory approach

Benefits

28. Nil.

Costs

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

Risks and assumptions

30. We have assumed that industry is already keeping a certain amount of the new data required, e.g. site of manufacture of imported articles, and that they have efficient data retrieval systems. Industry has been aware of 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 was received in response to the formal consultation exercise.

[2] European Commission Impact Assessment

Affected groups and size of industry

31. The Directive extends responsibilities to include all EOs in the supply chain.

32. NBs offer certification and approval services to their clients. They also vary widely in terms of their size. A Notified Body's capacity to respond to the changes presented by the new Directive can therefore vary widely.

33. NBs will be affected due to the reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations. UK-wide 8 NBs will be affected by the ATEX Directive and colleagues in GB have advised that none of these are in Northern Ireland.

34. It is not possible to estimate the size of the ATEX 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 estimated the industry's turnover, and, if apportioned on the basis of the UK population as a proportion of EU population turnover in the UK could be around £0.3 billion. If a similar apportionment is carried out for NI's population relative to that in the UK[3], this would equate to an estimated figure of £8.4 million. It is estimated in the EU IA that approximately 90% of the companies in this sector are SMEs.

Direct costs to business

35. 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 given an indication of costs and impact according to different elements of the supply chain.

36. 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 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 the existing Directive. 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 suggest 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).

[3] Office for National Statistics overview of the UK population shows that Northern Ireland's population is 2.8% of the UK total.

37. 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.

38. 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[4].

39. 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.[5]

40. 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. No comment was received in response to the formal consultation exercise.

41. 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.

42. 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.

Table: Sector Definition and Industry Size

Directive	ATEX
Examples of products	Mechanical, electrical and telecommunication equipment, protective systems and devices, to be used in potentially explosive atmospheres
Size of industry (EU market output)[6]	€2.2 billion
Size of industry (UK) (GVA)	£0.3 billion (estimate)[7] (around £8.4 million in Northern Ireland (estimate))
Industry Structure in UK	*A large number of SME and micro enterprises, around 90% of which are based in France, Germany and the UK*
No. UK Businesses[8]	Not obtainable
No. UK employees[9]	Not obtainable
No. NBs (EU)[10]	55
No. of NBs (UK)	8

[4] European Commission Impact Assessment 2011
[5] European Commission Impact Assessment 2011
[6] EU New Legislative Framework (NLF) Alignment Package Impact Assessment, 2011
[7] ABI (ONS, Annual Business Inquiry), 2009
[8] ABI, 2009
[9] ABI, 2009
[10] EU New Legislative Framework (NLF) Alignment Package Impact Assessment, 2011

Direct impacts on NBs

43. 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 Directive will be charged a fee by the UK Accreditation Service (UKAS). There are 8 NBs for ATEX in the UK. We are not aware of any NBs in Northern Ireland.

44. If we assume that assessment under the new Directive 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

45. 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.

46. NBs may elect to recuperate the cost of accreditation through their charges to business but the evidence on this point is not strong. No additional information was received through the formal consultation process.

Small and Micro Business Assessment

47. We do not have specific information on small firms operating within the sector. 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.

48. 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.

49. A longer transition period and/or specific guidance for smaller firms are not considered necessary as firms within the affected sector 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 exercise has not provided any information to suggest that small or micro businesses will have any difficulties in complying with these amendments.

Direct benefits to business

50. 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.

51. 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.

52. 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.

53. 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

54. The traceability obligations of the Directive will facilitate the identification of EOs having marketed non-compliant products. This may reduce the cost of investigations for enforcement bodies and we will seek to gain more information about this through the consultation.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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.

Wider impacts

60. Economic impacts: better functioning of the internal market, competitiveness of EU firms, and 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.

61. 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).

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

Formal Consultation

63. As part of the call for evidence during the formal consultation exercise we sought comments on the conclusions in the consultation impact assessment. In particular we asked –

(a) Do you expect any benefits from the proposed changes? If so, what would they be; what evidence do you have for them; and how great would they be?; and

(b) (i) Do you consider that the proposed Regulations are effective and proportionate? If not, please explain why you think this is the case. (ii) Do the proposed Regulations impose requirements which go beyond the requirements set out in the ATEX Directive and which you consider to be disproportionate or unnecessary? If so, please explain why you think this is the case.

(c) Does the Impact Assessment adequately reflect the effect of the ATEX Directive?

(d) Do you agree with our estimate of the number of businesses affected? Can you provide additional evidence?

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

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

64. No comments were received in response to the consultation.

Summary and preferred option

65. 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.

66. 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 that the Directive 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.

67. We would implement by bringing in secondary legislation to revoke and replace the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996.

68. 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 2017. Copy out will be used in transposing the Directive where possible, however it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty.

Health and Safety Executive for Northern Ireland
15 June 2017