EXPLANATORY MEMORANDUM TO

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

S.R. 2017 No. 90

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department for the Economy (DfE) to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972 and is subject to the negative resolution procedure.

1.3 The Rule is due to come into operation on 10 July 2017.

2. Purpose

2.1 The Rule will implement Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres, which was required to be transposed by 20 April 2016.

2.2 The Rule will replace and repeal the current Regulations (the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996 (S.R. 1996 No. 247) as amended).

3. Background

What is being done and why

3.1 Directive (94/9/EC) on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres provided the technical requirements that ensure the safety of equipment and protective systems for use in potentially explosive atmospheres. It was reviewed and aligned with the New Legislative Framework (NLF). NLF consists of EU Decision 768/2008/EC on a Commission Framework for the Marketing of Products and EU Regulation 765/2008/EC on requirements for accreditation and market surveillance relating to the marketing of products.

3.2 The NLF seeks to apply a number of principles across all Single Market Product Directives:

- to address the number of non-compliant products that reach the market through improved traceability and clearer requirements on manufacturers, importers and distributors to co-operate with enforcement authorities;

- to address inconsistent performance between Notified Bodies through a reinforced notification process; and

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

3.3 The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017 ("the Regulations") correspondingly repeal and replace the provisions in the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996 to align UK rules with NLF. There are no changes to the technical requirements for equipment under the Regulations.

3.4 The Statutory Rule copies out the relevant parts of the revised Directive.

4. Consultation

4.1 The Health and Safety Executive for Northern Ireland ("HSENI") ran a public consultation exercise from 18 March 2016 to 16 May 2016. There were approximately 500 consultees, including individuals and bodies representative of section 75 of the Northern Ireland Act 1998 and other organisations with an interest in equality and related issues (including each member of the Northern Ireland Assembly). The Consultation Document was also posted on the HSENI website.

4.2 During the consultation period 1 formal reply was received. The respondent made no substantive comments.

4.3 A summary of the outcome of the consultation exercise can be found on the HSENI website by clicking here.

5. Equality Impact

5.1 The Statutory Rule has been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998 and no adverse or differential aspects were identified.

6. Regulatory Impact

6.1 An Impact Assessment was carried out in respect of the Statutory Rule and is attached to this memorandum at Annex A.

7. Financial Implications

7.1 Overall costs and benefits are anticipated to be modest given that this is an alignment of existing legislation rather than an introduction of any new requirements.

7.2 Since this is an EU driven proposal, these costs are unavoidable.

8. Section 24 of the Northern Ireland Act 1998

8.1 The Department has considered the matter of Convention rights and is satisfied that there are no matters of concern.

9. EU Implications

9.1 The Statutory Rule will implement Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2016 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres.

9.2 A Transposition Note appears at Annex B to this Memorandum.

10. Parity of Replicatory Measure

10.1 In Great Britain the corresponding Statutory Instrument is the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (S.I. 2016/1107), which was made on 15 November 2016 and came into force on 8 December 2016.

11. Additional Information

11.1 The Statutory Rule will be supported by guidance produced by the Department for Business, Energy and Industrial Strategy (BEIS) which has been adopted for use in Northern Ireland. This will be published on the BEIS website at http://www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy.

11.2 The European Commission has produced detailed guidance on the provisions of Directive 2014/34/EU and its requirements which can be found here under the heading "Where can I find further guidance or support?". The Commission's Blue Guide provides guidance on horizontal issues.

Department for the Economy
May 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.

<u>Costs</u>

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 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[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.

[2] European Commission Impact Assessment

No further information was received in response to the formal consultation exercise.

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-

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

off costs (the data retention costs and some traceability requirements will be on-going).

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

[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

No. NBs (EU)[10]	55
No. of NBs (UK)	8

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.

[10] EU New Legislative Framework (NLF) Alignment Package Impact Assessment, 2011

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
May 2017

ANNEX B

NORTHERN IRELAND TRANSPOSITION NOTE FOR THE IMPLEMENTATION OF DIRECTIVE 2014/34/EU – TRANSPOSED BY THE EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS (NORTHERN IRELAND) 2017 (S.R. 2017 NO.90)

1. This Transposition Note has been prepared by the Department for the Economy and is intended to explain how the 2014 Directive is implemented in Northern Ireland.
2. The Regulations are being made in order to implement the provisions of the revised EU Directive on equipment and protective systems intended for use in potentially explosive atmospheres ("ATEX") (2014/34/EU), which entered into force on 20 April 2016.
3. The Regulations will replace and repeal the current Regulations (the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996, S.R.1996 No. 247).
4. The Regulations do not go beyond what is necessary to implement the 2014 Directive.
5. The Health and Safety Executive for Northern Ireland ("the Executive") is responsible for taking measures to implement the 2014 Directive.

TRANSPOSITION OF DIRECTIVE 2014/34/EU

Article	Objective of the Article	Implementation
1(1)	The Directive applies to products	Regulation 3(1)
1(2)	Products that are not within the scope of the Directive	Regulation 3(3)
2	Definitions	Regulations 2 and 3(2) Article 2(26) defines "CE marking" by reference to the purpose of the marking. Regulation 7(1) specifies that the CE marking must be applied after a successful conformity assessment, but before an article is placed on the market.
3(1)	Obligation to take all appropriate measures to ensure that products may be made available on the market and put into service when in conformity with the requirements of the Directive.	Unnecessary to implement this Article explicitly. The Regulations as a whole prevent the placing on the market or the putting into service of products which do not comply with the essential safety requirements.
3(2)	This Article permits Member States to lay down requirements necessary to ensure that individuals, in particular workers are protected when using products.	Unnecessary to implement this explicitly. This provision is implemented by using the freedom provided to Member States to implement domestic health and safety legislation as appropriate.

ANNEX B

Article	Objective of the Article	Implementation
3(3)	Exception from the Directive allowing showing and use of products at trade fairs, exhibitions and demonstrations for marketing purposes.	Regulation 4 and Part II of the Health and Safety at Work (Northern Ireland) Order 1978
4	Obligation that products must meet the essential health and safety requirements set out in Annex II of the Directive	Regulation 2(1) and Part 2 (Obligations of economic operators)
5	Obligation not to obstruct free movement of products which satisfy the requirements of the Directive.	Unnecessary to implement this explicitly. This provision is implemented by ensuring that domestic legislation does not obstruct free movement.
6(1)	Manufacturers must ensure that products have been designed and manufactured in accordance with the essential health and safety requirements.	Regulation 5
6(2)	Obligation 1: Manufacturers must draw up technical documentation and have a relevant conformity assessment procedure carried out. Obligation 2: Once a product has, by means of a relevant conformity assessment, been demonstrated to be in conformity with the essential health and safety requirements, the manufacturer must draw up an EU declaration of conformity and affix the CE marking. Obligation 3: Once a component has, by means of a relevant conformity assessment, been demonstrated to be in conformity with the essential health and safety requirements, the manufacturer must draw up a written attestation of conformity. Obligation 4: Manufacturers must ensure that each product is accompanied by a copy of the EU declaration of conformity or the attestation of conformity. Obligation 5: Where a large number of products are delivered to a single user, the batch may be accompanied	Obligation 1: Regulation 6 Obligation 2: Regulation 7(1) Obligation 3: Regulation 7(3) Obligation 4: Regulation 7(4) Obligation 5: Regulation 7(5)

Article	Objective of the Article	Implementation
	by a single copy.	
6(3)	Manufacturers must keep technical documentation and the EU declaration of conformity (or where applicable, the attestation of conformity) for 10 years after the product has been placed on the market	Regulation 8
6(4)	Obligation 1: Manufacturers must ensure that procedures are in place to ensure that products manufactured by series production remain in conformity with the requirements of the Directive. Obligation 2: Changes in product design, characteristics, harmonised standards or other technical specifications must be adequately taken into account. Obligation 3: When deemed appropriate with regard to the risks presented by a product, manufacturers must, carry out certain monitoring activities (sample testing and investigative monitoring) and keep a register of complaints. Obligation 4: Manufacturers must keep distributors informed of monitoring activities.	Obligation 1: Regulation 9(1) Obligation 2: Regulation 9(2) Obligation 3: Regulation 10 Obligation 4: Regulation 10(1)(c)
6(5)	Obligation 1: Manufacturers must ensure that products placed on the market bear a type, batch or serial number so that they can be identified. Obligation 2: If the product does not contain sufficient space for the type, batch or serial number, the manufacturer must ensure that the information is provided on the packaging or in a document accompanying the product.	Obligation 1: Regulation 11(1) Obligation 2: Regulation 11(2)
6(6)	Save for products which are components, manufacturers must ensure that products placed on the market bear the specific marking of explosion protection, and where	Regulation 12

Article	Objective of the Article	Implementation
	applicable the other markings referred to in Annex II of the Directive.	
6(7)	Manufacturers must indicate their name, registered trade name or trademark and postal address on products in a language easily understood by end-users and market surveillance authorities. Where it is not possible to do this, the information must be put on packaging or in a document accompanying the article.	Regulation 13
6(8)	Manufacturers must ensure that a product is accompanied by instructions and safety information in a language which can be easily understood by end-users as determined by the Member State concerned. The instructions/safety information must be clear and understandable.	Regulation 14
6(9)	Obligation 1: Manufacturers who consider or have reason to believe that they have placed on the market a product not in conformity with the Directive must immediately take corrective action to bring that product into conformity, to withdraw it or recall it. Obligation 2: Where a product presents a risk, manufacturers must immediately inform the competent national authorities of the Member States in which the product has been made available to that effect, giving details of the non-compliance and any corrective measures taken.	Obligation 1: Regulation 15(1) Obligation 2: Regulations 15(2)
6(10)	Obligation 1: Manufacturers must, further to a reasoned request, provide a market surveillance authority with information and documentation necessary to demonstrate the conformity of a product with the Directive in a language which can be easily understood by the market surveillance authority.	Obligation 1: Regulation 16(1)

Article	Objective of the Article	Implementation
	Obligation 2: Manufacturers must cooperate with the authority on action taken to eliminate risks posed by products placed on the market.	Obligation 2: Regulation 16(2)
7(1)	Obligation 1: A manufacturer may, by written mandate, appoint an authorised representative. Obligation 2: The manufacturer's obligation as laid down in Article 6(1) of the Directive (design and manufacture in accordance with the essential health and safety requirements) and Article 62(2) (obligation to draw up technical documentation) of the Directive must not form part of the authorised representative's mandate.	Obligation 1: Regulation 17(1) Obligation 2: Regulations 17(3)
7(2)	Obligation 1: An authorised representative must perform the task specified in the mandate received from the manufacturer. Obligation 2: The mandate must allow the authorised representative to do at least the following: (a) keep the EU declaration of conformity (or the attestation of conformity) and the technical documentation for the market surveillance authority for 10 years; (b) provide the competent national authority with all the information and documentation to demonstrate the conformity of a product; and (c) cooperate with the competent national authorities on any action to eliminate the risks posed by products covered by the authorised representative's mandate.	Obligation 1: Regulation 17(2) Obligation 2: Regulation 17(4) To avoid duplication and repetition, instead of copying out the authorised representative's obligations, the regulation simply cross-refers to regulation 8 and regulation 16 which already sets these out.
8(1)	Importers must place only compliant products on the market.	Regulation 18
8(2)	Obligation 1: Before an importer places a product on the market, the importer must ensure that the manufacturer has satisfied certain	Obligation 1: Regulation 19

Article	Objective of the Article	Implementation
	obligations and that the product is accompanied by the required documents. Obligation 2: Where an importer considers, or has reason to believe, that a product is not in conformity with the essential health and safety requirements, the importer must not place it on the market. Obligation 3: Where the product presents a risk, the importer must inform the manufacturer and the market surveillance authorities.	 Obligation 2: Regulation 20(1) Obligation 3: Regulation 20(2)
8(3)	Obligation 1: Importers must indicate their name, registered trade name or registered trade mark and address on the product. Obligation 2: If that is not possible, the information must be indicated on the packaging or in an accompanying document. Obligation 3: The information must be in a language which can be easily understood by end-users and market surveillance authorities.	Obligation 1: Regulation 21(1) Obligation 2: Regulation 17(3) Obligation 3: Regulation 21(2)
8(4)	Importers must ensure that a product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned.	Regulation 22
8(5)	Importers must ensure that while a product is under their responsibility, they do not jeopardise its compliance with the essential health and safety requirements.	Regulation 23
8(6)	Obligation 1: When deemed appropriate with regard to the risks presented by a product, importers must, carry out certain monitoring activities and keep a register. Obligation 2: Importers must keep distributors informed of monitoring activities.	Obligation 1: Regulation 24(1)(a) and (b), 24(2), 24(3) Obligation 2: Regulation 24(1)(c)

Article	Objective of the Article	Implementation
8(7)	Obligation 1: Importers who consider or have reason to believe that they have placed on the market a product not in conformity with the Directive must immediately take corrective action to bring that product into conformity, to withdraw it or recall it. Obligation 2: Where a product presents a risk, importers must immediately inform the competent national authorities of the Member States in which the product has been made available to that effect, giving details of the non-compliance and any corrective measures taken.	Obligation 1: Regulation 25(1) Obligation 2: Regulation 25(2)
8(8)	Importers must keep the technical documentation and the EU declaration of conformity (or where applicable the attestation of conformity) for 10 years after the product is placed on the market.	Regulation 27
8(9)	Obligation 1: Importers must, further to a reasoned request, provide a competent national authority with information and documentation necessary to demonstrate the conformity of a product with the Directive in a language which can be easily understood by the market surveillance authority. Obligation 2: Importers must cooperate with the authority on action taken to eliminate risks posed by products placed on the market.	Obligation 1: Regulation 26(1) Obligation 2: Regulation 26(2)
9(1)	When making a product available on the market, distributors must act with due care.	Regulation 28
9(2)	Obligation 1: Before a distributor makes a product available on the market, the distributor must ensure that the manufacturer and importer have satisfied certain obligations and that the product is accompanied by the required documents. Obligation 2: Where a distributor considers, or has reason to believe,	Obligation 1: Regulation 29 Obligation 2: Regulation 31(1)

Article	Objective of the Article	Implementation
	that a product is not in conformity with the essential health and safety requirements, the distributor must not make it available on the market. Obligation 3: Where the product presents a risk, the distributor must inform the manufacturer or the importer and the market surveillance authorities.	 Obligation 3: Regulation 31(2)
9(3)	Distributors must ensure that while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements.	Regulation 30
9(4)	Obligation 1: Distributors who consider, or have reason to believe, that a product which they have made available on the market is not in conformity must make sure that corrective measures are taken to bring that article into conformity, withdraw it or recall it. Obligation 2: Where the product presents a risk, the distributor must immediately inform the competent national authorities of the Member States in which they made the product available.	Obligation 1: Regulation 32(1) Obligation 2: Regulation 32(2)
9(5)	Obligation 1: Distributors must, further to a reasoned request, provide a competent national authority with information and documentation necessary to demonstrate the conformity of a product with the Directive Obligation 2: Distributors must cooperate with the authority on action taken to eliminate risks posed by products made available on the market.	Obligation 1: Regulation 33(1) Obligation 2: Regulation 33(2)
10	Importers and distributors to be treated as manufacturers where they place a product on the market under their name or trademark or modify it in a way that affects its compliance	Regulation 34

Article	Objective of the Article	Implementation
	with the Directive.	
11	Economic operators must, on request identify other economic operators in the supply chain. They must be able to do this for 10 years after the supply of a product occurs.	Regulation 35
12(1)	Products presumed to be in conformity with the essential safety requirements to the extent that they are in conformity with a harmonised standard covering those requirements.	Regulation 38
12(2)	In the absence of harmonised standards, Member States must take any steps necessary to bring to the attention of the parties concerned of existing national standards and technical specifications relevant to the implementation of essential health and safety requirements.	Unnecessary to implement this explicitly.
13(1)	When assessing the conformity of equipment, and where necessary, the devices referred to at Article 1(1)(b), the procedure to be followed must be one of the procedures listed.	Regulation 39(1)
13(2)	The procedure for the conformity assessment of protective systems must be either the procedure referred to at point (a) or (d), Article 13(1) of the Directive	Regulation 39(2)
13(3)	Obligation 1: The procedures listed at Article 13(1) of the Directive must be applied in respect of components, with the exception of affixing of the CE marking and the drawing up of the EU declaration of conformity. Obligation 2: The manufacturer must issue a written attestation of conformity, declaring: (a) the conformity of the components with the applicable provisions of the Directive; (b) the component's characteristics and how they must be incorporated into equipment or protective systems to assist with compliance with the	Obligation 1: Regulation 39(3)(a) Obligation 2: Regulation 39(3)(b)

Article	Objective of the Article	Implementation
	essential health and safety requirements applicable to finished equipment or protective systems.	
13(4)	In addition to the conformity assessment procedures set out in Articles 13(1) and (2) of the Directive, the conformity assessment procedure referred to in Annex VIII of the Directive may also be followed.	Regulation 39(4)
13(5)	Where the conformity assessment procedures have not been applied, the competent authorities may, on a justified request, authorise the placing on the market and the putting into service of the products in the territory of the Member State concerned, where the use is in the interest of protection.	Regulation 39(5)
13(6)	The documents and correspondence relating to the conformity assessment procedures must be drawn up in a language determined by the Member State concerned.	Regulation 39(6)
14(1)	The EU declaration of conformity must state that the fulfilment of the essential safety requirements has been demonstrated	Regulation 40(a)
14(2)	Obligation 1: The EU declaration of conformity must have the model structure set out in Annex X of the Directive. Obligation 2: The EU declaration of conformity must contain the elements specified in the relevant procedures set out in Annex III to IX of the Directive. Obligation 3: The EU declaration of conformity must be continuously updated. Obligation 4: The EU declaration of conformity must be translated into the language required by the Member State in which the product is placed or made available on the market.	Obligation 1: Regulation 40(b) Obligation 2: Regulation 40(c) Obligation 3: Regulation 7(2) Obligation 4: Regulation 37
14(3)	Obligation 1: Where a product is subject to more than one Union act	Obligation 1: Regulation 7(6)

Article	Objective of the Article	Implementation
	requiring an EU declaration of conformity, a single declaration must be drawn up. Obligation 2: The declaration must contain the identification of the Union acts concerned.	 Obligation 2: Regulation 7(6)
14(4)	By drawing up the EU declaration of conformity, the manufacturer assumes responsibility for the compliance of the product with the requirements of the Directive.	It is unnecessary to implement this requirement. The manufacturer has a clear set of obligations under the Regulations, which each have their own trigger points (such as placing on the market).
15	The CE marking is subject to the general principles in Article 30 of Regulation (EC) No 765/2008	Regulation 41 This obligation has been implemented by setting out the principles contained in Article 30 of Regulation (EC) No 765/2008 as enforceable prohibitions.
16(1)	Obligation 1: The CE marking must be affixed visibly, legibly and indelibly to the product or its data plate. Obligation 2: Where that is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging and to the accompanying documents.	Obligation 1: Regulation 41(1) Obligation 2: Regulation 41(2)
16(2)	The CE marking must be affixed before the product is placed on the market.	Regulation 7(1)(b)
16(3)	Obligation 1: The CE marking must be followed by the identification number of the notified body, where that body is involved in the production control phase. Obligation 2: The identification number must be affixed by the body itself, or under its instruction, by the manufacturer or the authorised representative.	Obligation 1: Regulation 41(3) Obligation 2: Regulation 41(4)
16(4)	The CE marking, and where applicable, the identification number of the notified body, must be followed by the specific marking of explosion protection, the symbols of the	Regulation 41(5)

Article	Objective of the Article	Implementation
	equipment-group and category and, where applicable, the other markings and information referred to in point 1.0.5 of Annex II of the Directive.	
16(5)	Obligation 1: The CE marking may be followed by any other mark indicating a special risk or use. Obligation 2: Products that are designed for a particular explosive atmosphere must be marked accordingly.	Obligation 1: It is not necessary to implement this Article. This is a permissive provision, which is unnecessary in the absence of a relevant prohibition. Obligation 2: Regulation 41(6)
16(6)	Member States must build on existing mechanisms to ensure correct application of the regime governing CE marking and must take appropriate action in the event of improper use.	Regulation 36 This provision requires action, but does not specify the action that must be taken. The UK implements this obligation by prohibiting the improper use of the CE marking, and in particular by enforcing the requirements set out in Article 30 of Regulation (EC) 765/2008.
17	Member States must notify the Commission and other Member States of bodies authorised to carry out third-party conformity assessment tasks.	Regulations 42(1) and 39
18(1)	Member States must designate a notifying authority which is to be responsible for assessment and notification of conformity assessment bodies and the monitoring of notified bodies.	Regulations 44, 46, 48 and 50
18(2)	Member States may decide that the assessment and monitoring is to be carried out by a national accreditation body.	Regulation 47 It is not necessary to implement this provision explicitly. The United Kingdom is using this flexibility to allow the Health and Safety Executive for Northern Ireland ("the Executive") to carry out assessments and monitoring.
18(3)	Obligation 1: Where the notifying authority delegates the assessment, notification or monitoring of a conformity assessment body, that body shall be a legal entity.	Regulation 47 Obligation 1: The United Kingdom Accreditation Service is a registered legal company limited by guarantee.

Article	Objective of the Article	Implementation
	Obligation 2: The legal entity must comply with the requirements in Article 19 of the Directive. In addition, it shall have arrangements to cover liabilities arising out of its activities.	Obligation 2: It is not necessary to implement the obligation to comply with the requirements in Article 19 of the Directive for the reasons set out in the table below relating to Article 19.
18(4)	The notifying authority must take full responsibility for the tasks performed by the body referred to in Article 18(3).	It is not necessary to implement this explicitly. The Executive will satisfy this obligation by operating in accordance with the Memorandum of Understanding between the UK Government and the United Kingdom Accreditation Service.
19(1)	A notifying authority must be established in such a way that no conflict of interest with conformity assessment bodies occurs	It is not necessary to implement this explicitly. The Executive does not have a conflict of interest with conformity assessment bodies.
19(2)	A notifying authority must be organised and operated so as to safeguard the objectivity and impartiality of its activities.	It is not necessary to implement this explicitly. The Executive will satisfy this obligation by operating in an objective and impartial manner.
19(3)	A notifying authority must be organised so that each decision on notification is taken be competent persons, different from those who carried out the assessment	It is not necessary to implement this explicitly. It is expected that the United Kingdom Accreditation Service will carry out the assessment and the Executive (operating through officials) will decide on notification.
19(4)	A notifying authority must not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.	It is not necessary to implement this explicitly. This obligation will be satisfied by the Executive not performing such services on a commercial or competitive basis.
19(5)	A notifying authority must safeguard the confidentiality of the information it obtains.	It is not necessary to implement this explicitly. The Executive will satisfy this obligation by maintaining confidentiality.
19(6)	A notifying authority must have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.	It is not necessary to implement this explicitly. The Executive will satisfy this obligation by ensuring that they have a sufficient number of competent personnel to perform his tasks.
20	Obligation 1: Member States must inform the Commission of their	Obligation 1: Regulations 44(7) and 46(2)

Article	Objective of the Article	Implementation
	procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies. Obligation 2: The Commission shall make that information publicly available	 Obligation 2: It is not necessary to implement this. The obligation falls with the Commission and not the Member State.
21(1)	For the purposes of notification, a conformity assessment body must meet the requirements in paragraphs 2 to 11.	Regulation 44(4)
21(2)	A conformity assessment body must be established under the national law of a Member State and have legal personality.	Schedule 2, paragraph 1
21(3)	Obligation 1: A conformity assessment body must be third-party body independent of the organisation or the product it assesses. Obligation 2: A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered a body.	Obligation 1: Schedule 2, paragraph 2 Obligation 2: Schedule 2, paragraph 3
21(4)	Obligation 1: A conformity assessment body, its top level management and the personnel responsible for carrying out conformity assessment tasks must not be the designer, manufacturer, supplier, owner etc. of the products. Obligation 2: A conformity assessment body, its top level management and the personnel responsible for carrying out conformity assessment tasks must not be directly involved in the design, manufacture, marketing etc. of the products. They must not engage in	Obligation 1: Schedule 2, paragraph 4 Obligation 2: Schedule 2, paragraphs 5 and 6

Article	Objective of the Article	Implementation
	any activity which may conflict with their independence or integrity. Obligation 3: Conformity assessment bodies must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.	 Obligation 3: Schedule 2, paragraph 7
21(5)	Conformity assessment bodies must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence and must be free from pressures and inducements which might influence their judgement.	Schedule 2, paragraph 8
21(6)	Obligation 1: A conformity assessment body must be capable of carrying out the conformity assessment tasks assigned to it and in relation to which it has been notified. Obligation 2: A conformity assessment body must have at its disposal: (a) personnel with technical knowledge and sufficient experience; (b) the descriptions of procedures in accordance with which conformity assessment is carried out; (c) the procedure for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, the degree of complexity of the product technology etc. Obligation 3: A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner.	Obligation 1: Schedule 2, paragraph 9 Obligation 2: Schedule 2, paragraph 10 Obligation 3: Schedule 2, paragraph 11
21(7)	The personnel responsible for carrying out conformity assessment tasks must have: (a) sound technical and vocational	Schedule 2, paragraph 12

Article	Objective of the Article	Implementation
	training covering all the conformity assessment activities; (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority; (c) appropriate knowledge and understanding of the essential health and safety requirements, the relevant harmonised standards and legislation; (d) the ability to draw up certificates, records and reports.	
21(8)	Obligation 1: The impartiality of the conformity assessment bodies, their top level management and the personnel responsible for carrying out conformity assessment tasks must be guaranteed. Obligation 2: The remuneration of the top level management and personnel responsible for carrying out conformity assessment tasks must not depend on the number of assessments carried out or on the results of the assessments.	Obligation 1: Schedule 2, paragraph 13 Obligation 2: Schedule 2, paragraph 14
21(9)	Conformity assessment bodies must take out liability insurance unless liability is assumed by the State or the Member State is responsible for the conformity assessment.	Schedule 2, paragraph 15
21(10)	Obligation 1: The personnel of a conformity assessment body must observe professional secrecy, except in relation to the competent authorities of the Member State in which it is carrying out its activities. Obligation 2: Proprietary rights must be protected.	Obligation 1: Schedule 2, paragraphs 16 and 17 Obligation 2: Schedule 2, paragraph 16
21(11)	Conformity assessment bodies must participate in, or ensure that their personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group and must apply as general guidance the administrative decisions and documents produced by that group.	Schedule 2, paragraph 18
22	Where a conformity assessment body	Regulation 43

Article	Objective of the Article	Implementation
	demonstrates its conformity with the criteria laid down in relevant harmonised standards, it is to be presumed to comply with the requirements set out in Article 21 in so far as the applicable harmonised standards cover those requirements.	
23(1)	Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it must ensure that the subcontractor or the subsidiary meets the requirements set out in Article 21 and must inform the notifying authority accordingly.	Regulation 50(2)
23(2)	Notified bodies must take full responsibility for the tasks performed by subcontractors or subsidiaries.	Regulation 50(5)
23(3)	Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.	Regulation 50(3)
23(4)	Notified bodies must keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them.	Regulation 50(4)
24(1)	A conformity assessment body must submit an application for notification to the notifying authority of the Member State in which it is established.	Regulation 44(2) and (3)
24(2)	The application must be accompanied by a description of the conformity assessment activities, the conformity assessment module and the products for which the body claims to be competent, as well as by any accreditation certificate issued by a national accreditation body.	Regulation 44(2) and (3)
24(3)	Where the conformity assessment body cannot provide an accreditation certificate, it must provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements in Article 21.	Regulation 44(2) and 44(3)(c)
25(1)	Notifying authorities may notify only	Regulation 44(1), (2), (4) and (6)

Article	Objective of the Article	Implementation
	conformity assessment bodies which have satisfied the requirements in Article 21.	and regulation 2(1)
25(2)	They must notify the Commission and other Member States using the electronic notification tool developed and managed by the Commission.	Unnecessary to implement explicitly. The Executive will satisfy this obligation by actually making the notifications using the electronic notification tool.
25(3)	The notification must include full details of the conformity assessment activities, the conformity assessment module and product concerned and the relevant attestation of competence.	Regulation 46
25(4)	Where a notification is not based on an accreditation certificate, the notifying authority must provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that the body is monitored regularly and will continue to satisfy the requirements laid down in Article 21.	Regulation 45(c)
25(5)	The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or other Member States within 2 weeks, where an accreditation certificate is used, or 2 months otherwise. Only such a body is to be considered a notified body for the purposes of this Directive.	Regulations 42(1)(b) and 39
25(6)	The notifying authority must notify the Commission and other Member States of any subsequent relevant changes to the notification.	Regulation 48(4)
26(1)	Obligation 1: The Commission must assign an identification number to a notified body. Obligation 2: It must assign a single such number even where the body is notified under several Union acts.	It is not necessary to implement these obligations because these are obligations on the European Commission.
26(2)	Obligation 1: The Commission must make publicly available the list of notified bodies.	It is not necessary to implement these obligations because these are obligations on the European Commission.

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	Obligation 2: The Commission must ensure that the list is kept up to date.	
27(1)	Obligation 1: Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 21 or that it is failing to fulfil its obligations, the notifying authority must restrict, suspend or withdraw notification, depending on the seriousness of the failure. Obligation 2: The notifying authority must immediately inform the Commission and the other Member States.	Obligation 1: Regulation 48(1), (2), and (3) Obligation 2: Regulation 48(4)
27(2)	In the event of a restriction, suspension or withdrawal of notification, or where the notified body has ceased activity, the notifying Member State must take appropriate steps to ensure that the files are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities.	Regulation 48(5)
28(1)	The Commission must investigate any doubts regarding the competence of a notified body or whether the body is fulfilling its responsibilities.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
28(2)	The notifying Member State must provide the Commission, on request, with information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.	It is not necessary to implement this obligation explicitly. The Executive will satisfy this obligation by providing any such information that is requested.
28(3)	The Commission must ensure that all sensitive information obtained in the course of its investigations is treated confidentially.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
28(4)	Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for notification, it must adopt an implementing act requesting the notifying Member State to take the necessary corrective action.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
29(1)	Notified bodies must carry out conformity assessments in	Regulation 49 and Schedule 3, paragraph 1

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	accordance with the conformity assessment procedures set out in Annex III to VII and Annex IX.	
29(2)	Obligation 1: Conformity assessments must be carried out in a proportionate manner. Obligation 2: Conformity assessment bodies must perform their activities taking due account of the size of the undertaking, the sector in which it operates, its structure, the degree of complexity etc. Obligation 3: In doing so they must respect the degree of rigour and level of protection required for the compliance of the product with the requirements of the Directive.	Obligation 1: Regulation 49 and Schedule 3, paragraph 2 Obligation 2: Regulation 49 and Schedule 3, paragraph 3 Obligation 3: Regulation 49 and Schedule 3, paragraph 4
29(3)	Where a notified body finds that essential health and safety requirements set out in Annex II or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it must require the manufacturer to take appropriate corrective measures and must not issue a certificate of conformity.	Regulation 49 and Schedule 3, paragraph 5, 8 and 9
29(4)	Where, in the course of monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate, if necessary.	Regulation 49 and Schedule 3, paragraph 6
29(5)	Where corrective measures are not taken or do not have the required effect, the notified body must restrict, suspend or withdraw any certificates.	Regulation 49 and Schedule 3, paragraph 7, 8 and 9
30	Member States must ensure that an appeal procedure against decisions of the notified body is available.	Regulation 49 and Schedule 3, paragraph 11
31(1)	Notified bodies must inform the notifying authority of: (a) any refusal, restriction, suspension or withdrawal of a certificate; (b) any circumstances	Regulation 49 and Schedule 3, paragraph 10

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	affecting the scope or conditions for notification; (c) any request for information received from market surveillance authorities; and (d) on request, conformity assessment activities performed etc.	
31(2)	Notified bodies must provide other bodies notified under the Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.	Regulation 49 and Schedule 3, paragraph 12
32	The Commission must provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
33	Obligation 1: The Commission must ensure that appropriate coordination and cooperation between notified bodies are put in place. Obligation 2: Member States must ensure that the bodies notified by them participate in the forum.	Obligation 1: It is not necessary to implement this obligation because it is an obligation on the European Commission. Obligation 2: Regulation 49 and Schedule 3, paragraph 13
34	Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 apply to products.	Part 5 and Schedules 4 and 5. Regulation (EC) 765/2008 is directly applicable in United Kingdom law. Part 5 of these Regulations provides for enforcing authorities to use their powers to give effect to Regulation (EC) 765/2008.
35(1)	Obligation 1: Where a market surveillance authority has reason to believe that a product presents a risk to the health or safety of persons or to domestic animals or property, it must carry out an evaluation in relation to the product concerned. Obligation 2: The relevant economic operators must cooperate as necessary with the market surveillance authorities for the purposes of the evaluation.	Obligation 1: Regulations 55 and 2(5) Obligation 2: Regulations 16(2)(a), 26(2)(a) and 33(2)(a)

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	Obligation 3: Where, in the course of an evaluation, the market surveillance authority finds that a product does not comply, it must require the economic operator to take all appropriate corrective action within a reasonable period. Obligation 4: The market surveillance authority must inform the relevant notified body accordingly. Obligation 5: Article 21 of Regulation (EC) No 765/2008 applies to the corrective action required.	Obligation 3: Regulation 56(1) and (7) Obligation 4: Regulation 56(2) Obligation 5: Regulation 56(3)
35(2)	Where the market surveillance authority considers that non-compliance is not restricted to their national territory, they must inform the Commission and other Member States of the result of the evaluation and the actions that it has required of the economic operator.	Regulation 56(3)
35(3)	The economic operator must ensure that all appropriate corrective action is taken in respect of all products concerned made available on the market.	Regulations 16(2)(b), 26(2)(b) and 33(2)(b)
35(4)	Obligation 1: Where the relevant economic operator does not take adequate corrective action, the market surveillance authority must take appropriate measures to prohibit or restrict the products being made available on the national market, to withdraw the product from the market or to recall it. Obligation 2: The market surveillance authority must inform the Commission and the other Member States of those measures.	Obligation 1: Regulation 56(4) Obligation 2: Regulation 56(5)
35(5)	Obligation 1: The information provided to the Commission and other Member States must include certain information, including data necessary for the identification of the non-compliant product, the origin of	Obligation 1: Regulation 56(6)

Article	Objective of the Article	Implementation
	the product, the nature of the non-compliance and the risk, the nature of the national measures taken etc. Obligation 2: The information provided must indicate whether the non-compliance is due to either failure to meet requirements under the Directive or shortcomings in the harmonised standards.	 Obligation 2: Regulation 56(6)
35(6)	Member States other than the one initiating the procedure must inform the Commission and other Member States of any measures adopted and any information at their disposal relating to the non-compliance of the product, and any objections to the adopted national measure.	Regulation 57(1)
35(7)	If no objections are raised within 3 months of receipt of the information, the measure is considered justified.	It is not necessary to implement this provision. It concerns a procedure that takes place at the EU level.
35(8)	Member States must ensure that appropriate restrictive measures are taken in respect of a product without delay.	Regulation 57(2)
36(1)	Where, on completion of the procedure in Article 35, objections are raised, the Commission must enter into consultation, evaluate the national measure, adopt an implementing act determining whether the national measure is justified and communicate its decision to Member States and relevant economic operators.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
36(2)	Obligation 1: If the national measure is considered justified, all Member States must take the necessary measures to ensure that the non-compliant product is withdrawn from their national market and inform the Commission accordingly. Obligation 2: If the national measure is considered unjustified, the Member State concerned must withdraw that measure.	Obligation 1: Regulation 57(3) and (4) Obligation 2: Regulation 57(5)
36(3)	Where the national measure is	It is not necessary to implement

Article	Objective of the Article	Implementation
	considered justified and the non-compliance is attributed to a shortcoming in the harmonised standards, the Commission must apply the procedure provided for in Regulation (EU) No 1025/2012.	this obligation because it is an obligation on the European Commission.
37(1)	Where, having carried out an evaluation, a Member State finds that although a product is in compliance with the Directive, it presents a risk to the health or safety of persons or to domestic animals or property, it must require the relevant economic operator to take all appropriate measures to ensure that the product, when placed on the market, no longer presents the risk, to withdraw the product or to recall it within a reasonable period.	Regulations 58(1) and (4) and 2(5)
37(2)	The economic operator must ensure that corrective action is taken in respect of all the products concerned that the economic operator has made available on the market throughout the Union.	Regulations 16(2)(b), 26(2)(b) and 33(2)(b)
37(3)	The Member State must inform the Commission and other Member States and provide the data necessary to identify the product, the origin and the supply chain, the nature of the risk and the nature of the national measures taken.	Regulation 58(2) and (3)
37(4)	The Commission must enter into consultation, evaluate the national measures and decide whether the national measure is justified by way of implementing acts.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
37(5)	The Commission must address its decision to all Member States and the relevant economic operators.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
38(1)	Where a Member State makes a finding of formal non-compliance, it must require the relevant economic operator to put an end to the non-compliance concerned.	Regulation 59(1) and (4)
38(2)	Where the non-compliance persists, the Member State must take appropriate measures to restrict or	Regulation 59(2) and (3)

Article	Objective of the Article	Implementation
	prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.	
39(1)	The Commission is to be assisted by the Committee on equipment and protective systems intended for use in potentially explosive atmospheres.	It is not necessary to implement this obligation because it is an obligation on the European Commission.
39(2)	Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 applies.	It is not necessary to implement this provision as it concerns a process at the EU level.
39(3)	Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 applies.	It is not necessary to implement this provision as it concerns a process at the EU level.
39(4)	Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011 applies.	It is not necessary to implement this provision as it concerns a process at the EU level.
39(5)	The committee must be consulted by the Commission and must examine matters concerning the application of the Directive raised by the chair or a representative of a Member State.	It is not necessary to implement this provision as it concerns a process at the EU level.
40	Member States must lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and must take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements. The penalties provide must be effective, proportionate and dissuasive.	Part 5 (and in particular, regulations 61 and 62)
41(1)	Member States must not impede the making available on the market of products which are in conformity with Directive 94/9/EC and which were placed on the market before 20 April 2016.	Regulations 3(3)(h) and 72(3)
41(2)	Certificates issued under Directive 94/9/EC are to be valid under the Directive.	Regulation 71
42(1)	Obligation 1: Member States must adopt and publish their implementing measures by 19 April 2016 and must	Obligation 1: It is not necessary to implement this obligation explicitly. This obligation is

Article	Objective of the Article	Implementation
	apply them from 20 April 2016. Obligation 2: Where Member States adopt the measures referred to in paragraphs 1 and 2, they must contain a reference to this Directive. They must also include a statement that references in existing laws to the Directive repealed are to be construed as references to the new Directive.	satisfied by implementing on time. Obligation 2: These Regulations do contain a reference to the Directive in regulation 2(1) and in the Explanatory Note. However, the obligation concerning references to the 1994 Directive is implemented by ensuring that there are no longer any references to the repealed Directive in United Kingdom law.
42(2)	Member States must communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	It is not necessary to implement this obligation explicitly. This obligation is implemented by communicating the main provisions to the Commission.
43	Directive 94/9/EC is repealed from 20 April July 2016.	It is not necessary to implement this obligation as it operates at the EU level. However, the Regulations do revoke the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996, the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations (Northern Ireland) 1999 and the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations (Northern Ireland) 2008, which implemented the repealed Directive.
44	The Directive enters into force the day following its publication and most provisions apply from 20 April 2016.	It is not necessary to implement this obligation as it operates at the EU level.
45	This Directive is addressed to Member States.	It is not necessary to implement this provision.
Annex I	Equipment Groups and Categories	Regulation 2(1) (by cross-reference to the Directive)
Annex II	Essential health and safety requirements	Schedule 1
Annex	Conformity assessment procedures –	Regulation 6 and Regulation 39

ANNEX B

Article	Objective of the Article	Implementation
III	Module B: EU-type examination	(by cross-reference to the Directive)
Annex IV	Conformity assessment procedures – Module D: Conformity to type based on quality assurance of the production process	Regulation 39(1)(a)(i) (by cross-reference to the Directive)
Annex V	Conformity assessment procedures – Module F: Conformity to type based on product verification	Regulation 39(1)(a)(ii) (by cross-reference to the Directive)
Annex VI	Conformity assessment procedures – Module C1: Conformity to type based on internal production control plus supervised product testing	Regulation 39(1)(b)(i)(aa) (by cross-reference to the Directive)
Annex VII	Conformity assessment procedures – Module E: Conformity to type based on product quality assurance	Regulation 39(1)(b)(i)(bb) (by cross-reference to the Directive)
Annex VIII	Conformity assessment procedures – Module A: Internal production control	Regulation 39(1)(b)(ii)(aa), Regulation 39(1)(b)(ii)(bb), Regulation 39(1)(c) and Regulation 39(4) (by cross-reference to the Directive)
Annex IX	Conformity assessment procedures – Module G: Conformity based on unit verification	Regulation 6(b)(iv) and Regulation 39(1)(d) (by cross-reference to the Directive)
Annex X	EU Declaration of Conformity	Regulation 40 and Schedule 6
Annex XI	Repeals and time limits for transposition referred to Article 43	It is not necessary to implement these provisions.
Annex XIII	Correlation table	It is not necessary to implement these provisions.