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|--|---|--|--|--|
| Title: Directive on The harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (The Radio Equipment Directive) IA No: Lead department or agency: Department for Business, Innovation and Skills Other departments or agencies: Ofcom DCMS | Impact Assessment (IA) | | | |
| | Date: 19/08/2015 | | | |
| | Stage: Development/Options | | | |
| | Source of intervention: EU | | | |
| | Type of measure: Secondary legislation | | | |
| Contact for enquiries: Kevin Lane 0207 215 1774 | | | | |
| Summary: Intervention and Options | | | RPC Opinion: RPC Opinion Status | |

| Cost of Preferred (or more likely) Option | | | | |
|---|----------------------------|--|------------------------------|----------------------|
| Total Net Present Value | Business Net Present Value | Net cost to business per year (EANCB on 2009 prices) | In scope of One-In, Two-Out? | Measure qualifies as |
| £m | £m | £m | No | NA |
| | | | No | NA |

What is the problem under consideration? Why is government intervention necessary?

The Directive on Radio and Telecommunications Terminal Equipment (RTTE) 1999/5/EC, as amended, regulates the safety, electromagnetic compatibility, and avoidance of harmful interference for RTTE products within the EU. This Directive will be replaced by Directive 2014/53/EU on Radio Equipment, designed to improve compliance, remove unnecessary burdens and align with the New Legislative Framework (NLF). This will help address the current lack of compliance, causing risks to consumers and the sub-optimal allocation of radio spectrum. The NLF alignment will, in particular, help improve traceability of products through the supply chain. Implementation of the new Directive is required by the EU treaties.

What are the policy objectives and the intended effects?

The Government supports the principles of both safety of radio equipment and the principles of the single market. The measures are in line with UK policy to retain high levels of public safety and protection of the radio spectrum. The bringing into scope of broadcast radio receivers e.g. TV Freeview Box has been broadly supported by industry and stakeholders and will help to ensure more efficient future use of the radio spectrum, a scarce resource. The removal of telecommunications terminal equipment e.g. wired telephone from scope has also been welcomed by industry. The NLF alignment for this Directive is consistent with the alignment of a number of other Directives.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: PREFERRED
 Make secondary legislation to implement the Directive - by revoking and replacing the existing legislation . This option has been chosen because it will allow the UK to meet its legal obligation to implement the Directives.

Option 2:
 Adopt a non-regulatory approach to implementing the Directives. This option was considered and discounted because it would not satisfy the UK's legal obligation to implement the Directives.

| | | | | | |
|--|---------------------|-----------------------|---------------------|----------------------|---------------------|
| Will the policy be reviewed? It will be reviewed. If applicable, set review date: 05/2021 | | | | | |
| Does implementation go beyond minimum EU requirements? | | | No | | |
| Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base. | Micro Yes | < 20 Yes | Small Yes | Medium Yes | Large Yes |
| What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent) | | | Traded: | | Non-traded: |

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description: Introduce legislation to implement the Radio Equipment Directive

FULL ECONOMIC ASSESSMENT

| Price Base Year | PV Base Year | Time Period Years | Net Benefit (Present Value (PV)) (£m) | | |
|-----------------|--------------|-------------------|---------------------------------------|----------------|----------------|
| | | | Low: Optional | High: Optional | Best Estimate: |

| COSTS (£m) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---------------|---|--|----------------------------|
| Low | Optional | Optional | Optional |
| High | Optional | Optional | Optional |
| Best Estimate | | | |

Description and scale of key monetised costs by 'main affected groups'

Insufficient data to monetise costs as number of firms affected unknown. For NLF changes costs likely to be in line with wider NLF IA - around £540 one-off cost per firm and ongoing costs of £1350 per firm.

Other key non-monetised costs by 'main affected groups'

There are a number of potential costs for economic operators (i.e. manufacturers, authorised representatives, distributors and importers) in view of the new responsibilities contained in the NLF. Possible additional costs could be attributed to the requirement for the use of Notified Bodies for those product categories that will move from the EMCD to the RED and only in very limited circumstances when a published harmonised standard is not used by the manufacturer to declare conformance.

| BENEFITS (£m) | Total Transition (Constant Price) Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---------------|---|--|-------------------------------|
| Low | Optional | Optional | Optional |
| High | Optional | Optional | Optional |
| Best Estimate | | | |

Description and scale of key monetised benefits by 'main affected groups'

Other key non-monetised benefits by 'main affected groups'

Manufacturers that comply with the Directive are expected to benefit from the proposed improvements in transparency and traceability because it should be more difficult for others to place non-compliant products on the market. The further restrictions on unfair competition should benefit UK manufacturers by removing more non-compliant, unsafe and cheap products from the internal market. The NLF alignment will bring benefits to both consumers, manufacturers, and enforcement authorities.

| | | |
|--|--------------------------|--|
| Key assumptions/sensitivities/risks | Discount rate (%) | |
|--|--------------------------|--|

BUSINESS ASSESSMENT (Option 1)

| | | | | |
|--|------------------|-------------|--------------------------|-----------------------------|
| Direct impact on business (Equivalent Annual) £m: | | | In scope of OITO? | Measure qualifies as |
| Costs: | Benefits: | Net: | No | NA |

Evidence Base (for summary sheets)

Problem under consideration

The Directive on Radio and Telecommunications Terminal Equipment (RTTE) 99/5/EC as amended regulates the safety, electromagnetic compatibility, and avoidance of harmful interference for RTTE products within the EU.

A proposal to revise the RTTE Directive was published by the European Commission in October 2012. The new Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (the Radio Equipment Directive) was published in the Official Journal on 22 May 2014. Member States have until the 13th June 2016 to transpose the Directive into national laws.

The new Directive will help to address the lack of compliance currently in European markets which can present potential risks for consumers and lead to sub-optimal allocation of the radio spectrum. The current RTTE Directive has struggled to keep pace with technological developments and provisions agreed within the new Directive should assist in this respect.

In seeking to address these issues the vulnerable position of some smaller enterprises must be taken into account. As in other EU industrial sectors, most companies (99%) belong in the small and medium enterprise category.

New Legislative Framework alignment

In 2006 the European Commission conducted a review of the way that the internal market for goods was working. The Commission found that though the harmonised legislation was working effectively across and within EU Member States experience showed that it could be significantly improved. 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 (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 to provide a framework to be used in future Union legislation to address these issues.

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 765/2008/EC and an EU Decision 768/2008/EC in July 2008. Over time all new approach directives are to be aligned to the NLF as they are revised. An "Alignment Package" was introduced to align nine existing EU Directives to the NLF with no other changes to the legislative requirements. For the Radio Equipment Directive, as technical changes were required, the Directive was revised separately from the Alignment Package.

The main provisions of the NLF are to introduce common definitions and responsibilities for Economic Operators i.e. manufacturers, importers and distributors. The NLF also clarifies what economic operators must do when a product is non-compliant e.g. distributors who suspect a product does not comply must take corrective action to make it compliant or take steps to recall it.

Rationale for intervention

Under the EU Treaties the UK is obliged to implement the new Directive into UK law. The Directive supports the proper functioning of the single market and promotes safety of radio equipment and avoidance of harmful interference to the radio spectrum and the UK fully supports these objectives.

Without harmonising the placing on the EU market of the products falling within its scope UK industry will be disadvantaged in its ability to export standard products which are acceptable in the EU.

Should the UK fail to transpose the Directive by the deadline set by the Commission (13th June 2016) we risk proceedings being pursued against the UK by the Commission which will result in a fine. The Directive does not allow for a non-regulatory approach and if we did not implement by way of transposing legislation, we would risk putting UK business at a competitive disadvantage.

On 23 June, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until the exit negotiations are concluded the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU. The assumptions used in this impact assessment have been chosen accordingly.

Policy Objective

The current regulatory approach has been successful and does not require fundamental change. However some adjustments are required in order to facilitate and simplify its application and enforcement and so improve the level of compliance.

The revised Directive is designed to improve the level of compliance with its requirements, to clarify and simplify the requirements and to help reduce unnecessary burdens for economic operators and public authorities while retaining the current high levels of public safety and protection of the radio spectrum.

The changes will bring equipment such as broadcast receivers (e.g. TV freeview box) clearly into the scope of the Directive and will remove from the scope fixed-line (wired) telecommunications terminals e.g. wired telephones. This should help to reduce existing ambiguity and unnecessary complexity. The revised Directive provides a framework for the use of innovative technologies e.g. software-defined radio equipment, with the caveat that only compliant combinations of software and hardware come together.

The simplification and reduction of administrative burdens includes the removal of the current requirement to notify the placing on the market of equipment using non EU-wide harmonised frequency bands and removal of the obligation to affix an equipment class identifier on the product. Responses to the earlier government consultation on the new Directive indicated that industry welcome this lightening of regulation.

The revised Directive is intended to enhance the functioning of the single market while at the same time making improvements to the directive whilst minimising additional costs to businesses especially micro businesses. However, without harmonising the placing on the EU market of the products falling within its scope UK industry will be disadvantaged in its ability to export standard products which are acceptable in the EU.

The new Directive will be aligned to the NLF. The requirements of the NLF are being introduced in all product sectors regulated under Union harmonisation legislation and it would be inconsistent and potentially confusing not to introduce them in this sector. The implementation will be carried out by way of copy out. There is no intention in transposing into national legislation to go further than is required by the Directive.

Despite close consultation with prominent UK Trade Associations and UK Enforcement Authorities it has proved difficult to obtain detailed data on the current breakdown of the scale and scope of the sector affected. The radio equipment sector is not separately identified within the official UK statistics suggesting that it is relatively small in scale. The EU IA suggests that 75% of production in the UK is attributed to a small number of large firms but that there are also a large number of smaller players, both producers and importers, who will be affected. The EU IA also suggests that the import of products within scope of the new Directive is increasing and therefore importers rather than domestic producers may be impacted most by the proposed changes, and most of the changes that will be of direct consequence to importers are attributable to the more general NLF alignment requirements rather than the specifics of the Radio Equipment Directive.

Many of the economic operators affected by changes to the new Directive would already be required to be in conformance with the current product safety Directives which cover this type of equipment, namely the Low Voltage Directive (LVD) and/or the Electromagnetic Compatibility Directive (EMCD). Both of these Directives form part of the wider NLF Alignment Package (an impact assessment on the provisions contained within the NLF Alignment has already been submitted to the RPC) and economic operators would be required to be compliant with the requirements detailed in the new LVD and EMCD. The major difference between the LVD/EMCD and the Radio Equipment Directive is that the Radio Equipment Directive requires the opinion of a Notified Body in cases where a published European harmonised standard has not been applied by a manufacturer or where a harmonised standard does not exist. Under the EMCD and LVD a manufacturer has the option to self-declare compliance rather than incur the extra cost associated with obtaining an opinion from a notified body. Any potential impact of this change will be limited as most manufacturers will use a published harmonised standard to meet the requirements of the Directive. In the limited cases where a published harmonised standard is not available for a particular type of equipment there could be an impact. The cost of using a Notified Body to examine a technical file varies but is usually in the region of c£500.00. Many large manufacturers already use in-house test labs and/or Notified Bodies in addition to the application of published harmonised standards to help prove compliance for corporate governance purposes. In the case of sound and TV broadcasting equipment, which will now be in scope of the Radio Equipment Directive, work is ongoing within the relevant European standards organisation (ETSI) to help ensure that suitable harmonised standards will be in place for the changeover date.

Many of the economic operators within the radio equipment sector also operate in the LVD and EMC sector, the largest of those affected by the NLF, which equates to £13.6 billion GVA and £31 billion in turnover with approximately 9000 enterprises employing 20,000 people (ABI, 2013 data).

Description of options considered

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

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

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

Option 2 – non-regulatory approach

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

Monetised and non-monetised costs and benefits of each option (including administrative burden)

Option 1 - make legislation to implement the Directives

Impact of changes to scope

Radio-determination equipment shall now fall within the scope of Directive 2014/53/EU.

The revised Directive now contains an explicit reference to include Radiodetermination (Radar) within its scope. This is not expected to significantly impact costs and benefits as the UK view has been that the scope of the current RTTE Directive already includes Radiodetermination products thereby maintaining the status quo. This view is supported by a European Commission Decision agreed in the technical Committee for the R&TTED (TCAM) and is supported by an explicit reference to the inclusion of Radar contained in Section 1.3.2 of the current Guidance.

Sound and TV receive-only equipment which is excluded from Directive 1999/5/EC, shall now fall within the scope of Directive 2014/53/EU

This is expected to have a direct impact on manufacturers of this type of equipment due to the potential for more stringent technical requirements in the future. The inclusion of this equipment within the new Directive has been agreed but industry still has the flexibility to agree any new technical requirements for inclusion within harmonised standards which should help mitigate some of the impacts of this change. However any future impact is expected to be off-set by increased revenue received from new allocations to in-demand radio services e.g. 4G/5G and mobile broadband, and more efficient and effective re-farming of the radio spectrum. The increased availability of new and re-allocated radio spectrum is expected to be of indirect benefit to manufacturers who will benefit by having increased flexibility to develop and provide new products that require increased radio spectrum to operate effectively e.g. new mobile broadband services and products for 'the internet of things' e.g. smart domestic appliances.

An appropriate regime for regulating receiver performance is increasingly necessary to avoid interference between users and increase spectrum efficiency as spectrum is redeployed from one user to another, for example for use with new mobile broadband services.

The inclusion of broadcasting receivers within the scope of the Directive will provide a basis on which manufacturers could agree on implementing key improvements which are vital as governments re-allocate more radio spectrum from traditional analogue broadcast services (post-Digital Dividend) to other services like mobile broadband.

The inclusion of sound and broadcast receivers will reduce the impact of ongoing difficulties in releasing new bands for mobile broadband and great difficulty in packing as many users into available spectrum because of the co-existence issues arising from TVs and sound broadcasting receivers that are overly susceptible to interference from users in adjacent frequencies.

There will be a direct benefit in revenues from future spectrum auctions and also from the growth in economic activity and innovation that radio spectrum enables.

During the transition period, two years from the date the Directive enters into force, there would be no change for existing products and any product which was compliant with the RTTE Directive and placed on the market during this transition period would be unaffected by the requirements of the Radio Equipment Directive. The product life cycle for TV and radio equipment is now extremely short and most manufacturers introduce new products regularly in order to stay competitive in a fast-changing market. The consequence of this being that nearly all new products to market for TV and radio are already within scope of the current RTTE Directive.

The reason for this being that more recent designs of TVs and some radios contain built-in wireless (wi-fi) capability and are therefore already covered by the existing RTTE Directive. Only when the industry has agreed on a new EU harmonised standard, would the Directive have any new regulatory effect on TVs and sound broadcasting radios. The main trade group for the UK television equipment industry is the Digital TV Group and it has notified BIS that they agree that this change is needed. Reputable manufacturers will continue to see conformity to the current EU standard as the key to opening up markets for their products. It is possible though that some lower quality equipment made outside the EU for other markets will be excluded from the EU through the effect of the Radio Equipment Directive, but this could be an important consumer protection measure as most consumers are quite unable to judge whether one receiver is technically better than another.

Software Defined Radio

A new Article is included in the Directive to address radio equipment whose characteristics can be changed by the application of software. This will help to facilitate innovation and the use of future technology with the caveat that the combinations of hardware and software must ensure overall compliance with the Directive. It is not possible to provide any detailed analysis of the impacts or costs and benefits at this stage as the technical characteristics and operational procedures are the subject of an Implementing Act and Delegated Act and have yet to be decided. Software Defined Radio is an emerging market and is expected to expand rapidly in the future. The European Commission will be required to provide a new impact assessment to effect any regulatory change in respect of this.

Registration of Radio Equipment

The Directive contains the potential for a future requirement for manufacturers to register certain categories of radio equipment in a central database. The categories of radio equipment required to be registered and the operational procedures are the subject of an Implementing Act and Delegated Act and it is not currently possible to fully assess the impact, costs and benefits. To implement any future changes to the legislation the European Commission will be required to provide an evidence base and produce a new impact assessment.

Electronic Labelling

The Directive contains a recital to allow for the exploration of the future possibility to fulfil the labelling and marking requirements electronically i.e. by use of the electronic display. This is welcomed by industry and has the potential to significantly reduce current administrative burdens.

Removal of Administrative Provisions/Burdens

Notification Procedure

The requirement to notify the use of non-EU wide harmonised frequencies has been removed and this will reduce the administrative burden currently placed on economic operators.

Equipment Class Identifier

The Directive has removed the requirement to affix an equipment class identifier on the product which will reduce the burden to manufacturers during the marking phase of production.

Simplified Declaration of Conformity

The new Directive contains an Article allowing for manufacturers to provide a simplified declaration of conformity (DoC) to meet the provisions of the Directive. This should be of direct benefit to industry who will be able to provide a short DoC including an internet address advising of where the full details of the DoC can be found. This will remove the requirement to include increased paperwork to accompany products when placed on the market. This provision is not included in other Directives as part of the NLF Alignment Package.

New Legislative Framework

Some of the costs to economic operators that can be attributed to the new Directive are as a consequence of changes that form part of the wider NLF Alignment. Annex A provides further detail on the costs and benefits that can be directly attributed to the NLF.

Summary of Main Changes

| Area of Impact | Cost/Benefit |
|--|---|
| Radio-determination equipment clarified to fall within the scope of Directive 2014/53/EU. | No impact – this type of equipment considered to already be within scope of current RTTE Directive |
| Sound and TV receive-only equipment which is excluded from Directive 1999/5/EC, shall now fall within the scope of Directive 2014/53/EU | Potential direct impact to sound and TV broadcast equipment manufacturers (of which we believe there is only one in the UK) – significant benefit to radio spectrum authorities and providers of mobile and mobile broadband services |
| Software Defined Radio | Potential benefit – full impact to be determined with new EU IA |
| Registration of Radio Equipment | Cost/Benefit subject to a new IA before implementation |
| Electronic Labelling | Potential (significant) benefit |
| Removal of requirement for Equipment Class Identifier | Benefit |
| Simplified Declaration of Conformity | Benefit |
| Removal of Notification Procedure | Benefit |

Direct benefits to business

There could be marginal benefits to organisations wishing to become Notified Bodies from a clearer indication of the notification process. Additionally some benefits are expected from clarifications and harmonisation of definitions across Member States, though it is not possible to quantify these.

Simplified Declaration of Conformity

The new Directive contains an Article allowing for manufacturers to provide a simplified declaration of conformity (DoC) to meet the provisions of the Directive. This should be of direct benefit to industry who will be able to provide a short DoC including an internet address advising of where the full details of the DoC can be found. This will remove the requirement to include increased paperwork to accompany products when placed on the market. This provision is not included in other Directives as part of the NLF Alignment Package.

Background to Impact Assessment

This impact assessment has been drawn up with help from Ofcom the market surveillance agency for the RTTED. DCMS has also been involved in the analysis of the impacts of the inclusion of broadcast receivers. However, the IA relies heavily in the assumptions made in the EU IA. We have not been able

to obtain clearer details on the monetised impact to manufacturers in the UK due to the large number of independent micro enterprises.

In the planned consultation on the implementation of the Directive, it is hoped that more information will be drawn from stakeholders to improve the analysis where possible. This includes asking stakeholders for their comments on the impact of the New Legislative Framework, for areas where we do not have any detailed analysis. We will also draw on the responses to the consultation on the NLF alignment package.

Informal consultation has already taken place with large manufacturers in the sector who have provided major input throughout the process. The forthcoming consultation will focus on penalties and a renewed effort to obtain further information on the major costs and benefits of the new Directive, in particular the costs and benefits to small and medium enterprises including importers and distributors.

Summary and preferred option and description of implementation plan

Option 1 – make legislation to implement the Directives – PREFERRED

This will align the Directive to the NLF; achieve the objectives of the Directive and meet our obligation under EU law to implement the Directive.

Despite consultation with the sector it has not been possible to identify the number of businesses affected by the changes to the RED. We believe that there is only one UK manufacturer of sound and TV receiving equipment but the number of importers and distributors of such equipment also affected by the RED changes and the particularly the NLF changes is unknown. It has not been possible therefore to monetise the likely costs and benefits of the changes and further information will be sought via the RED consultation and the NLF consultation already underway.

The NLF impact assessment provides further information on the possible costs per firm of the proposed changes in sectors such as EMC/LV that are similarly affected by the NLF changes (one off costs of £540 per firm and on-going costs of £1350 per firm per year).

Implementation Plan

- A formal consultation will take place in [-] 2017 and BIS will ask stakeholders for their views on whether the UK Impact Assessment is an adequate estimation of the costs and benefits of implementing the Directive into UK law.
- This IA will be revised if required in response to that consultation with the aim of obtaining final clearance from the Reducing Regulation Committee in April 2017.
- Guidance on the Regulations is expected to be published in May 2017.
- The European Commission will be notified of the implementation in May 2017
- UK Regulations to implement the Directive should be laid in May 2017 and should enter into force on [-].
- The final transposition deadline in the Directive was 13th June 2016.
- The UK must report to the European Commission on the operation of the Directive by 12 June 2017 and every two years thereafter.

Annex A

New Legislative Framework

Costs to Business Directly Attributed to the New Legislative Framework Alignment

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 economic operators in the supply chain – need to keep information for 10 years | <u>Partially.</u> Economic operators 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. | Economic Operators Market Surveillance Authorities | <u>Medium.</u> 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 great 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 economic operators will be expected to retain information about products which are no longer on the market. |
| Reinforcement of notification requirements and exchange of information | <u>Partially.</u> Notified Bodies are already required to exchange information, however the obligation has been widened and so exchanges will need to be more frequent. | Notified bodies | <u>Medium.</u> There is high awareness among UK NBs of the new Directives, however some may be less familiar with the detail than others. | Facilitated exchanges between notified bodies 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 | <u>Partially</u> Manufacturers and importers are already obliged to include identifying information on products but the amount required will increase | Manufacturers Importers Market Surveillance Authority | <u>Medium.</u> 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. |

| | | | | |
|--|---|---|---|---|
| Post marketing obligations (sample testing, keeping a register of complaints etc.) | <u>Partially.</u> Some bodies already have these systems in place however those who do not will need to establish them. | Manufacturers Importers Market Surveillance Authorities | <u>Medium.</u> 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

The legislative environment in the EU is complex and inconsistent, with products often being regulated by several legal instruments with different objectives. For example many of the products that are covered by the Radio Equipment Directive are also subject to other horizontal EU legislation such as RoHS (Restrictions on Hazardous Substances), WEEE (Waste Electrical and Electronic Equipment), REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals and EuP (ecodesign for Energy Using Products).

Manufacturers must currently comply with all of these requirements, meaning that they incur additional costs. The introduction of a set of common requirements will make it easier for all economic operators to understand their obligations as these will vary less 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 those that manufacture products and retailers who supply "own brand" products, who will be clearly obliged to meet the same requirements. This will have positive implications for competition.

Increased responsibility of importers

Consumers will be better protected, as importers will have an increased role in ensuring that only safe products are placed on the market – currently it is relatively easy for an importer to import and then distribute containers of goods without knowing the extent to which they comply with legislation because they rely on the word of the manufacturer or agent that the goods comply with the applicable legislation. The alignment also broadens the obligations of the importers by, for example, including a new obligation to their name on packaging, and a new obligation to verify that the product has been conformity assessed. 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

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 facilitate more effective market surveillance of products. The obligations on importers to retain Declarations of Conformity for a longer period of time and to have access to the technical documentation should ensure that only complying products are placed on the market.

Notification process

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

Some British Trading Standards departments have indicated they do not receive a large number of complaints about unsafe or potentially unsafe products from consumers (though it should be borne in mind that consumers may not approach them directly and in some cases not complain at all) and they do not therefore envisage much in the way of financial benefit accruing to consumers from the proposed amendment, although this should nevertheless reduce such complaints.

Increased business and financial savings for Notified Bodies

There may be financial savings and additional business for some Notified Bodies in the short term. Where products are certified by accreditation 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

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.

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

Overarching Costs

Retention of information

There will be a duty for all economic operators to keep information for ten years as to who supplied them with a product and who they have supplied a product to. Some of the products may have a lifespan of less than ten years. The additional data collection and storage cost is expected to be marginal given that much of it will be now stored electronically and many firms will already keep some records, but we will test this assumption via the consultation exercise and if further evidence indicates otherwise, it will be reported accordingly.

Change of Directive number

A new Directive number might lead to minor logistical difficulties and costs being incurred for manufacturers and notified bodies necessitating the re-drafting and re-issue of documents and manuals to include the revised number. Those involved in writing standards will also be involved in discussions on how the standards should cross-refer to legislation. There will be a transitional period before these requirements will come into force hence any alterations could be incorporated more broadly into periodic updating. While we would not expect the additional cost associated with the redrafting and reissue to be significant some stakeholders have raised this as a concern; we therefore intend to test our assumption through the consultation.

Notification process

NBs for the industries concerned could be affected due to reinforcement of the notification requirements and information obligations – strengthened obligations on information sharing among notified bodies would lead to some increase in on-going costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent. NBs that we have spoken to already have not suggested that this will impose significant costs.

Familiarisation costs

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 which we will seek further clarity on through the consultation.

Table: Summary of key costs and estimated impact

| Change | Is this a new requirement? | Bodies affected | Estimated level of awareness of the change (High/Medium/Low) | Description of the cost |
|--|--|---|--|--|
| Retention of information – need to keep information for 10 years | <u>Partially.</u> Economic operators are already required to retain some information however the requirement will be broadened. In some cases concerned will have a life span of less than 10 years. | Economic Operators Market Surveillance Authorities | <u>Medium.</u> Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations. | The costs with collecting and retaining additional data is expected to be marginal. |
| Change of Directive number | <u>Yes</u> | All | <u>High.</u> 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 | <u>Partially.</u> Notified Bodies are already required to exchange information, however the obligation has been widened and so exchanges will need to be more frequent. | Notified bodies | <u>Medium.</u> There is high awareness among UK NBs of the new Directives, however some may be less familiar with the detail than others. | <u>We do not expect this to be a significant cost.</u> Exchanges between NBs already occur, although these will increase. |
| Traceability requirements | <u>Partially</u> Manufacturers and importers are already obliged to include identifying information on products but the amount required will increase | Manufacturers Importers Market Surveillance Authority | <u>Medium.</u> 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 | <u>Partially.</u> Some bodies already | Manufacturers Importers | <u>Medium.</u> Trade Associations, for example, | 42% of Economic Operators and 23% of |

| | | | | |
|---|--|---------------------------------|---|---|
| (sample testing, keeping a register of complaints etc.) | have these systems in place however those who don't will need to establish them. | Market Surveillance Authorities | will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations. | SMEs attribute no/no significant cost increase. 30% of Economic Operators and 18% SMEs attribute a significant cost increase. |
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