

**Regulatory Impact Analysis (RIA)**

**EUROPEAN UNION (ELECTROMAGNETIC  
COMPATIBILITY) REGULATIONS 2016**

**To Transpose**

**Directive 2014/30/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 electromagnetic compatibility  
(recast)**

**Department of Jobs, Enterprise & Innovation**

**April 2016**

## Summary of RIA

Summary of Regulatory Impact Analysis (RIA)			
<b>Department/Office</b> Enterprise Agencies and Programmes Unit Department of Jobs, Enterprise & Innovation		<b>Title of Legislation</b> European Union (Electromagnetic Compatibility) Regulations 2016	
<b>Stage</b> Transposition of Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014		<b>Date</b> April 2016	
<b>Related Publications</b> Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 European Communities (Electromagnetic Compatibility) Regulations 2016 European Communities (Electromagnetic Compatibility) Regulations 2007 Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC			
Available for download at: <a href="http://www.djei.ie">www.djei.ie</a> Directive 2014/30/EU is available at <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0030&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0030&amp;from=EN</a>			
<b>Contact for enquiries:</b> Bill Wall Email: <a href="mailto:bill.wall@djei.ie">bill.wall@djei.ie</a>			
<p>Directive 2014/30/EU seeks to guarantee the free movement of electrical equipment whilst creating an acceptable electromagnetic environment within the EU and is a recast of Directive 2004/108/EC, which currently regulates this equipment and which was implemented in Ireland by the European Communities (Electromagnetic Compatibility) Regulations 2007.</p> <p>The Directive 2014/30/EU has the same scope as Directive 2004/108/EC, which it replaces. The major changes are that when it is transposed it will be simpler and more rational to apply, its scope clarified by means of improved definitions, additional powers will be available to recall apparatus, market surveillance will be improved through inter alia better traceability of the economic operators and it will be easier to implement as clearer enforcement powers are made available for the Commission for Communications Regulation (ComReg).</p> <p>Directive 2014/30/EU entered into force in April 2014 and applies from 20 April 2016 when Directive 2004/108/EC is repealed. A transitional period applies for apparatus, compliant with Directive 2004/108/EC, placed on the market before that date. The proposed European Union (Electromagnetic Compatibility) Regulations 2016 provide for the transposition of Directive 2014/30/EU and will replace the European Communities (Electromagnetic Compatibility) Regulations 2007.</p> <p>Option 1: No policy change. No change to the existing situation is included for benchmarking purposes.</p> <p>Option 2: Alignment of Directive 2014/30/EU by legislative measures.</p> <p><b>Preferred option:</b> Option 2: Alignment of Directive 2014/30/EU by legislative measures.</p>			
Options	Costs	Benefits	Impacts
1	Fine from EU	None	Directive 2004/108/EC, which the Regulations 2007 transposes, will be repealed in 2016.
2	Small or moderate additional costs.	Important benefits for stakeholders. Effective in reducing the number of non-compliant products and scope for unfair competition.	Coherent with the policy commitments underpinning Directive 2014/30/EU and addresses its objectives.

### **Statement of Policy Problem and Objective**

The EU has legislative requirements in its “technical harmonisation” directives for a vast range of products such as electrical products, machinery, etc. This legislation has two objectives:

- to ensure that products available in Europe safeguard public interests, such as the electromagnetic compatibility of products; and
- to ensure the free movement of products by replacing national rules with a single harmonised set of conditions for the marketing of the products concerned that apply in all EU Member States.

A stocktaking exercise on experience gained with the existing legislation in the harmonised area was carried out at EU level. The overall conclusion of this stocktaking was that the legislation has largely succeeded in liberalising trade in goods and in setting robust requirements ensuring the compliance of products. However, it also revealed a number of shortcomings, including a significant number of non-compliant products reaching the market.

To remedy shortcomings, the “New Legislative Framework” (NLF) was adopted and consists of two complementary instruments:

- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L218 of 13.08.2008.
- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L218 of 13.08.2008.

The Regulation, applicable since 1 January 2010, introduced rules on accreditation and requirements for the organisation and performance of market surveillance and controls of products from third countries.

The Decision contains model text that is meant to reinforce various provisions commonly used in EU product legislation (for example ‘definitions’, ‘obligations of economic operators’, ‘notified bodies’, etc) so that the legislation works more effectively in practice and introduces new aspects, such as more clearly outlining the obligations of importers, distributors, and the recall of non-compliant products if necessary, etc. The Decision, unlike the Regulation, does not have immediate legal effects on economic operators, individuals or Member States.

The Commission identified a specific set of product harmonisation directives for which alignment with the Decision could be dealt with as a 'package' (i.e. as opposed to individual alignments carried out at the same time as broader revisions). The alignment resulted in the adoption of Directive 2014/30/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 electromagnetic compatibility (recast), which seeks to guarantee the free movement of electrical equipment whilst creating an acceptable electromagnetic environment within the EU by ensuring that electromagnetic disturbances produced by electrical equipment do not effect the correct functioning of other such equipment, including telecommunication and electricity distribution networks, and that such equipment has an appropriate level of immunity to electromagnetic disturbances so that it can function as intended. Directive 2014/30/EU is a recast of Directive 2004/108/EC, which currently regulates this equipment

and was implemented in Ireland by the European Communities (Electromagnetic Compatibility) Regulations 2007. The recast procedure is used by the European Commission where there are no substantive changes involved in the proposal for a Directive.

Directive 2014/30/EU entered into force in April 2014 and applies from 20 April 2016 when Directive 2004/108/EC is repealed. A transitional period applies for apparatus, compliant with Directive 2004/108/EC, placed on the market before 20 April 2016. Directive 2014/30/EU must be transposed by 20 April 2016 and the proposed European Union (Electromagnetic Compatibility) Regulations 2016 will provide for its transposition and the revoking of the European Communities (Electromagnetic Compatibility) Regulations 2007.

### **Identification and Description of Options**

Where EU Directives leave policy choices to Member States in their implementation, the exercise of these choices may require primary legislation to give them effect. In general, Directive 2014/30/EU is drafted in mandatory terms requiring that Member States "shall" ensure specified things are done and there are no policy choices for the Member States in regard to what provisions must be implemented. In this regard, legal advice was sought on implementing Directive 2014/30/EU and it is agreed that the relevant Articles of the Directive may be transposed by way of regulations made under the European Communities Act 1972 (No. 27 of 1972).

The options for transposition are:

- Option 1: No policy change. This option consists of not introducing any changes to the existing situation.
- Option 2: Alignment of the Directive 2014/30/EU by legislative measures. This option consists of making new Regulations to transpose the Directive that would make use of the measures set out in the Directive.

### **Analysis of Costs, Benefits and other impacts for each option**

Option 1: No policy change. This option consists of not introducing any changes to the existing situation.

- The do nothing option is primarily being included for benchmarking purposes. Therefore it will not be examined in detail as part of this RIA because it is not envisaged that this option could be pursued in practice. To take no action would mean a failure to comply with Ireland's EU obligations and could result in prosecution by the European Commission.

Option 2: Alignment of Directive 2014/30/EU by legislative measures. This option consists of replacing the 2007 Regulations with new Regulations that would make use of the measures set out in the Directive. Under this option the new measures provided by these new Regulations can be summarised as follow:

- (1) Measures intended to address the problem of non-compliance:
  - Additional obligations are imposed on manufacturers, importers and distributors including traceability requirements throughout the whole distribution chain. Manufacturers and importers must put their name and address on the product and every economic operator must be able to inform the authorities from whom he purchased a product and to whom he supplied it.
  - Reorganisation of safeguard clause procedure (market surveillance) to clarify how the relevant enforcement authorities are informed about non-compliant

products and ensure that equivalent action is taken against that product in all Member States.

- (2) Measures intended to ensure the quality of notified bodies' work:
- Reinforcement of the notification requirements for notified bodies (including subcontractors and subsidiaries) such as impartiality and competence in carrying out their activity and application of guidance developed by coordination groups.
  - Revised notification process: Member States notifying a body must include information on the evaluation of the competence of that body. Other Member States can object to the notification within a certain period.
  - Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of notified bodies) such as objectivity and impartiality in carrying out their activity.
  - Information obligations: Notified bodies must inform notifying authorities of refusals, restrictions, suspensions and withdrawals of certificates.
- (3) Measures intended to ensure more consistency with other harmonisation directives:
- Alignment of commonly used definitions and terminology.
  - Alignment of the text of the conformity assessment procedures.

By using legislative measures, the provisions of Directive 2014/30/EU and the new Regulations transposing it would be binding obligations enforceable by the Commission for Communications Regulation (ComReg). This would give a strong guarantee that the positive impacts of the Directive would actually occur.

The legislative measures are not expected to have a significant impact on the costs of firms and notified bodies. Most of the additional obligations of economic operators complement existing obligations or codify what would be normal practice for a responsible/compliant firm (as opposed to those who cheat) according to the spirit of the existing legislation. Similarly, the requirements for notified bodies are fully in line with standards defining the relevant benchmark for the assessment of conformity assessment bodies. Overall an impact on costs is possible, in relation to obligations of importers/distributors and traceability, but is considered moderate. Due to the large variety of products covered by Directive 2014/30/EU, it is not possible to provide quantitative estimates. In this context, the EU's impact assessment showed there was no indication that the Directive might result in a disproportionate burden for SME.

As the alignment of Directive 2014/30/EU was a recast procedure, the proposed Regulations have no new implications for national competitiveness, the socially excluded and vulnerable groups, the environment, other economic impacts including a significant economic change in an economic market, the rights of citizens, compliance burden and North-South and East-West Relations.

In the light of its effectiveness, efficiency and coherence, option 2 stands out as the preferred option. The no policy change option 1 is not viable.

## Comparison of the listed options

	Effectiveness	Efficiency	Coherence
<b>Option 1:</b> <b>No change</b>	Not Viable	Not Viable	Incoherent with other New Legislative Framework (NLF) instruments as Directive 2004/108/EC is repealed in 2016.
<b>Option 2:</b> <b>Transpose Directive</b>	Effective in relation to the objectives of reducing the number of non-compliant products and scope for unfair competition as well as all the other commitments of the NLF.	Important benefits for stakeholders versus small or moderate additional costs.	Coherent with other NLF instruments and the policy commitments underpinning Directive 2014/30/EU.

## Consultation

A consultation was carried out by the EU, from June to October 2010, which was published on the Your Voice in Europe website, on the package of product harmonisation directives that were aligned to Decision No 768/2008/EC. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and the EU received 300 replies. In view of the high number of SME active in the sectors concerned, a specific SME consultation was carried out in addition to the general consultation. 603 SME were consulted through the Enterprise Europe Network in May/June 2010. Several bilateral meetings also took place with industry associations including the electro-technical sector. The Commission's minimum consultation standards were fully met. In general all stakeholders expressed wide-spread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring Notified Bodies.

## Transposition Options

The proposed European Union (Electromagnetic Compatibility) Regulations 2016 will provide for the transposition of Directive 2014/30/EU. As few choices are offered by Directive 2014/30/EU, there was little need for consultations with interested parties, other than ComReg, before a choice was made on which option to follow.

Most of the provisions of the Directive are mandatory for Member States to transpose so we are precluded from changing the substance in transposition. In this context, the intention is to adhere to the Directive to the greatest extent possible; close alignment with the provisions of the Directive should reduce the scope for misrepresentation or reinterpretation. It is important that in transposing EU rules into national law, economic operators are not unduly burdened by requirements that increase their administrative overhead or bureaucratic load. Our approach therefore is to avoid going beyond the minimum requirements to avoid placing Irish economic operators at a competitive disadvantage.

## Enforcement and Compliance

ComReg already has powers of enforcement under the current legislation. The new Regulations will provide additional powers of enforcement to ComReg, which is already resourced to implement the existing legislation.

When Directive 2014/30/EU is transposed by the European Union (Electromagnetic Compatibility) Regulations 2016, the legislation will be simpler and more rational to apply,

maintain a high level of protection from non-compliant apparatus and will be easier to enforce.

Under the CE mark and other labelling requirements of the new legislation, the manufacturer/importer will be responsible for establishing the conformity of their products and for the “CE” marking. The duties of other economic operators are also spelled out in the new legislation.

### **Review**

The evaluation of the effectiveness of the legislation at EU level will be based on the feedback received through the various cooperation mechanisms already established under the Directive to facilitate implementation (experts groups, administrative cooperation groups (ADCOs), notified body groups). The Commission will produce a comprehensive report on the functioning of market surveillance (Article 40 of Regulation (EC) No 765/2008) which will also allow conclusions to be drawn for evaluation.

### **Publication**

This RIA is available on the Department’s website.

Enterprise Agencies and Programmes Unit  
Department of Jobs, Enterprise & Innovation  
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