

## **Regulatory Impact Analysis (RIA)**

### **To Transpose into Irish Law**

**Directive 2014/32/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 the making available on the market of Measuring Instruments (recast).**

**by way of:**

#### **(a) Legal Metrology (Measuring Instruments) Bill 2017**

This Technical Bill is required to transpose Articles 1 and 3 of Directive 2014/32/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 the making available on the market of Measuring Instruments (recast), and

#### **(b) Statutory Instrument making Regulations under Section 3 of the European Communities Act 1972**

The other Articles of Directive 2014/32/EU can however, be transposed by way of a Statutory Instrument (S.I.) under Section 3 of the European Communities Act 1972.

**Department of Jobs, Enterprise & Innovation  
June 2017**

## Summary RIA

<b>Summary of Regulatory Impact Analysis (RIA)</b>	
<b>Department/Office</b> Department of Jobs, Enterprise & Innovation	<b>Title of Legislation</b> (a) Legal Metrology (Measuring Instruments) Bill 2017 and  (b) Legal Metrology (European Conformity Assessment of Measuring Instruments) Regulations 2017
<b>Stage</b> Internal draft	<b>Date</b> June 2017
<b><u>Current Legislation Regarding Measuring Instruments</u></b>  Legal Metrology (European Conformity Assessment of Measuring Instruments) Regulations 2007 (S.I. 160 of 2007).  The above Statutory Instrument transposed <b>Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments</b>  S.I. 160 of 2007 is enforced in Ireland by the Director of the Legal Metrology Service (located in the National Standards Authority of Ireland (NSAI)).	

### 1. Statement of Policy Problem and Objective

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

- to ensure that products available in Europe, such, as Measuring Instruments inter alia, safeguard public interests and facilitate fair trading; 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.

#### 1.1 Background

The “New Legislative Framework (NLF)” is part of a series of measures aimed at ensuring that products placed on the EU market meet the required level of public interest protection.

The European Commission proposed to align eight existing Directives (which deal with specific products) to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 (which set out a common framework for the marketing of products on the EU market) by using the Recast procedure.

One of the eight Directives is Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the the harmonisation of the laws of the Member States in relation to the making available on the market of Measuring Instruments (Recast).

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

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 had 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 these shortcomings, the “**New Legislative Framework**” (NLF) was adopted in 2008 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 above 2008 Regulation, applicable since 1 January 2010, introduced rules on Accreditation and requirements for the organisation and performance of Market Surveillance and Controls of products coming into the EU 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 European 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 recast procedure was used by the European Commission where there are no substantive changes involved in the proposal for a Directive.**

### **3. Identification and Description of Options**

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 Directive 2014/32/EU by legislative measures.** This option normally consists of making new Regulations to transpose the Directive that would make use of the measures set out in the Directive.

In general, Directive 2014/32/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. Such provisions can be transposed into Irish law by way of a Ministerial Statutory Instrument (S.I.) under Section 3 of the European Communities Act 1972.

#### **3.1 Policy choices for Member States (Articles 1 and 3 of Directive 2014/32/EU)**

The objective of the recast Directive, namely to ensure that measuring instruments placed on the EU market fulfil the requirements providing for a high level of protection of the public interests covered by this Directive while guaranteeing the functioning of the Internal Market

cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level.

The Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, Directive 2014/32/EU, does not go beyond what is necessary in order to achieve that objective.

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 that regard, the Department of Jobs, Enterprise and Innovation sought the advice of the Office of the Attorney General in relation to the transposition of Articles 1 and 3 of Directive 2014/32/EU. The Attorney General's Office has advised the Office of the Parliamentary Counsel to the Government (OPC) and this Department that:

- The optional provisions in Articles 1 and 3 **must be transposed separately through primary legislation by means of a stand-alone Technical Bill. A Schedule will be attached to the Bill, setting out the categories of measuring instruments and prescribed uses to which the Directive will apply.**
- The other Articles of Directive 2014/32/EU can however, be transposed by way of a Statutory Instrument (S.I.) under Section 3 of the European Communities Act 1972.

### **3.2 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, is not a realistic policy option and 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 2014/32/EU by legislative measures**

This option consists of replacing the 2007 Regulations (referred to above) with new Regulations that would provide the legal requirements for making use of the measures set out in the Directive.

Under this option the new measures provided by the new Technical Act and 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 measuring instruments and every economic operator must be able to inform the national authorities from whom he/she purchased a measuring instrument and to whom he/she supplied it.
- Re-organisation of safeguard clause procedure (Market Surveillance) to clarify how the relevant enforcement authorities are informed about non-compliant measuring instruments 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 sub-contractors 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 national body must include information on the evaluation of the competence of that body

(“Notified Body”). Other Member States can object to the notification within a certain period. Under the 2007 Regulations, Ireland’s Notified Body is the Legal Metrology Service (LMS). The LMS will continue to be the Notified Body under Directive 2014/32/EU.

- **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. The Department of Jobs, Enterprise and Innovation will continue to be the Notified Body under Directive 2014/32/EU.
- **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.

**3.3** By using legislative measures, the provisions of Directive 2014/32/EU and the Technical Bill and the new Regulations transposing it, would be binding obligations enforceable by the Director of the Legal Metrology Service – as currently is the case in relation to the 2007 Directive on Measuring Instruments, under the Legal Metrology (Measuring Instruments) Bill 2017.

This continued policy approach at national level would give a strong guarantee that the positive impacts of the Directive would actually occur.

**3.4** The legislative measures are not expected to have a significant impact on the costs of firms and Notified Bodies. Most of the additional obligations assigned to economic operators complement existing obligations or codify what would be normal practice for a responsible/compliant firm, (as opposed to those who might, for example, cheat by tampering with measuring instruments), 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.

**3.5 Overall, an impact on costs is possible, in relation to the obligations in relation to Importers/Distributors and Traceability, but is considered moderate.** Due to the large variety of measuring instruments covered by Directive 2014/32/EU, it is not possible to provide quantitative estimates.

#### **4. European Commission's Impact Assessment - November 2011**

**4.1** In this context, **the European Commission's Impact Assessment showed that there was no indication that the Directive might result in a disproportionate burden for SME's.**

**COMMISSION STAFF WORKING PAPER IMPACT ASSESSMENT – SEC (2011) 1376 final of 21 November 2011** can be accessed at the following web-link

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52011SC1376>

See in particular, **Table 5: Overview of the impacts attributed to the listed options page 53 and Section 10.8 on pages 72 to 74 on Measuring Instruments.**

**4.2** As the alignment of Directive 2014/32/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.

**4.3** **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: No change</b>	Not Viable	Not Viable	Incoherent with other New Legislative Framework (NLF) instruments as Directive 2004/22/EC was repealed in 2016.
<b>Option 2: 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 economic benefits for stakeholders versus small or moderate additional costs.	Coherent with other NLF instruments and the policy commitments underpinning Directive 2014/32/EU.

#### 4.4 Consultation

The EU Commission held a public consultation in 2010 on the 2004 Directive, and in 2011, produced a report on its operation, which included information on the public consultation, an SME survey, external consultants views and an assessment of the impacts of suggested changes to the Directive.

**Department of Jobs, Enterprise and Innovation**

**June 2017**