

**SINGLE MARKET TRANSPARENCY  
DIRECTIVE  
(Directive (EU) 2015/1535):  
an instrument of co-operation between EU  
institutions, Member States and enterprises  
to ensure the smooth functioning of the  
Single Market**

**A guide to the procedure for the  
provision of information in the  
field of technical regulations and of  
rules on Information Society services**

<http://ec.europa.eu/growth/tools-databases/tris/en/>

## **PREFACE**

The first edition of the present booklet was elaborated under the guidance of my predecessor, Ms Sabine Lecrenier, with the aim to bring EU law closer to those who use it and to help to enhance the exchange of information, dialogue and cooperation which has constituted a new community culture.

I would like to recognise the great work and the importance of this 2005 publication, which has assisted economic operators but also national and regional authorities for several years in their dealings with technical regulations, standards and Information Society services.

In order to take into account the many developments that have occurred since 2005, it is necessary to present a second, revised edition of the guide.

The most important development is the Treaty of Lisbon signed on 13 December 2007, which replaced the Treaty establishing the European Community with the Treaty on the Functioning of the European Union (TFEU).

Further, in 2015, a codification took place of what is now commonly known as the Single Market Transparency Directive (*i.e.* the present Directive (EU) 2015/1535 of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services).

Moreover, the case law of the European Court of Justice related to the interpretation and the implementation of the Directive has been completed by several important judgments.

It is also worth mentioning the experience gained through the nearly 11.000 notifications received since the first publication of the guide. For example, the industry's role in preventing new barriers to trade has been fundamental. As such, the online TRIS database now ensures transparency and cooperation through the online repository.

It is clear that the notification procedure needed an updated guidance, in order to continue serving the EU institutions, Member States and industry.

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[TO BE PRINTED ON THE BACK COVER OF THE BOOKLET]

This booklet is intended as a guide to the system set up to prevent barriers to the free movement of goods, the freedom of establishment and the freedom to provide services as far as Information Society services are concerned. The booklet provides a commentary on Directive (EU) 2015/1535, which implements this system. Each of the Directive's provisions is quoted in full and accompanied by a detailed commentary explaining its meaning and its implications for all interested parties: European Commission services, Member States, and present or potential economic operators within the European Union.

The booklet has been prepared by Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, and does not commit the Commission in any way. The text of Directive (EU) 2015/1535 is alone legally binding. Directive (EU) 2015/1535 is subject to the interpretation of the Court of Justice of the European Union.

The original language of this booklet is English.

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## **INTRODUCTION: DIRECTIVE (EU) 2015/1535, AN INSTRUMENT OF TRANSPARENCY AT THE SERVICE OF THE INTERNAL MARKET**

At the beginning of the 1980s, the Commission, basing itself on a Court of Justice ruling known as the “Cassis de Dijon” judgment, launched a new policy designed to complete the Internal Market on the basis of three concepts:

- Acceptance in each Member State of products lawfully marketed in the rest of the Community (“mutual recognition”);
- Harmonisation limited to important economic sectors covering, in particular, health, safety and the environment;
- A prevention-based approach to monitoring national regulations.

Since 1984, Directive 83/189/EEC<sup>1</sup> which, following two codifications, became first Directive 98/34/EC<sup>2</sup>, and then Directive (EU) 2015/1535<sup>3</sup>, has laid down a preventive mechanism, the scope of which has been progressively extended.

Today, the Member States of the European Union are obliged to notify to the Commission and to the other Member States any draft technical regulation concerning products and Information Society services before they are adopted in national law.

The concept was revolutionary at the time and has remained so.

The Directive is addressed to the Member States who have agreed to take part in a reciprocal transparency and monitoring system in the regulatory field. This initiative was original in several ways:

- The system is of a preventive nature: information is provided when technical regulations relating to products or rules on information society services are still at the draft stage, and may be amended in order to comply with the principles of the Single Market.
- It is not only the Commission which can examine and monitor the national draft texts through the operation of standstill periods, but also all the Member States; the latter have acknowledged the advantages of a procedure which allows for reciprocal influence over their legislative processes. The Treaty itself merely made provision for retrospective monitoring by the Member States, through the use of the more cumbersome infringement procedures which are rarely applied between Member States.

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<sup>1</sup> Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 109, 26.4.1983, p. 8).

<sup>2</sup> Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37).

<sup>3</sup> Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

- The system also permits national draft legislation to be put on ice for a certain period to facilitate discussion at EU level on the matter in the light of harmonisation initiatives. Moreover, by means of this legislative observatory, the real needs for harmonisation can be identified more easily.

The system, which got off to a slow start, has gained momentum and has provided the Commission, the Member States and enterprises with a window on the activities of national authorities in the technical field (e.g. rules relating to product composition, labelling, name, testing, etc., as well as rules relating to product life cycle through to disposal). The scope of the Directive has been progressively extended, so that it now covers all agricultural, fishery and industrially manufactured products and takes account of an ever growing number of provisions, in particular to prevent any measures which indirectly require compliance with technical specifications from slipping through the net. In 1998, the procedure was extended by Directive 98/48/EC to encompass rules on Information Society services.<sup>4</sup>

The geographical scope of the Directive was also gradually extended. Directive 98/34/EC, which was already implemented in part in the EFTA countries since 1990<sup>5</sup>, has also been partly extended to Turkey under the Association Agreement with that country<sup>6</sup>. The Directive has also provided a model for a Convention of the Council of Europe<sup>7</sup>.

The most recent codification in 2015 ensured that these changes are reflected in a single legal text.

The application of the notification procedure has given rise to new practices. An entire philosophy of information exchange, dialogue and cooperation has evolved between the Member States. This mechanism has also proved to be a formidable benchmarking tool which allows Member States to draw on the ideas of their partners in order to solve common problems regarding technical regulations, especially in newly regulated sector such as digital services and new technologies. Through this instrument, the Commission not only succeeds in removing provisions which are contrary to Union law, but also contributes to the formulation of provisions to be included into national legislation to ensure that economic operators are fully informed of their rights and permit application in practice of the principle of “mutual recognition”. This principle derives from the case

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<sup>4</sup> Directive 83/189/EEC was amended principally by Council Directive 88/182/EEC of 22 March 1988 (OJ L 81, 26.3.1988, p. 75) and by European Parliament and Council Directive 94/10/EC of 23 March 1994 (OJ L 100, 19.4.1994, p. 30). Directive 98/34/EC of 22 June 1998 codified Directive 83/189/EEC and all its subsequent amendments. Directive 98/34/EC has been substantially amended several times, and has been codified by Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 (OJ L 241, 17.9.2015, p. 1).

<sup>5</sup> The Agreement between the Member States of EFTA and the EEC laying down a procedure for the provision of information in the field of technical regulations entered into force in November 1990. The Agreement on the European Economic Area, applicable since 1 January 1994, subsequently incorporated Directive 83/189/EEC with the necessary adaptations. Switzerland, though not a signatory to this Agreement, continues to apply the procedure for the exchange of information. On 29 March 2019, the EEA Joint Committee adopted its Decision No 75/2019 incorporating Directive (EU) 2015/1535, with the necessary adaptations, into the EEA Agreement. It has entered into force for the EEA EFTA States on the 1<sup>st</sup> of December 2019.

<sup>6</sup> Agreement establishing an Association between the European Economic Community and Turkey (OJ C Vol. 16 No C 113, 24.12.1973) and Decision 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the customs union (OJ L 35, 13.12.1996, p. 1).

<sup>7</sup> Convention No 180 of the Council of Europe on Information and Legal Co-operation concerning "Information Society Services".

law of the Court of Justice of the European Union (CJEU) on the interpretation of Articles 34 to 36 thereof of the Treaty on functioning of the European Union (TFEU).

According to the principle of mutual recognition, each Member State must allow market access in its territory to any product lawfully marketed in another Member State. Restriction or denial of that right is subject to justification and is only possible where legitimate public interests, such as health and safety protection are at stake.

The Commission, following multiple requests from the Competitiveness Council, committed to more and better mutual recognition, and proposed a “Single Market Clause” which has an inherent political and legal importance. The “Single Market Clause” is contained in the Commission Communication COM(2017)787 final (“The Goods Package: Reinforcing trust in the single market”) of 19 December 2017<sup>8</sup> with a clear and unambiguous phrasing of the principle of mutual recognition. Member States are encouraged to reproduce in a systematic manner in their technical rules the following “Single Market Clause”<sup>9</sup>:

*“Goods lawfully marketed in another Member State of the European Union or in Turkey, or originating and lawfully marketed in an EFTA State that is a contracting party to the EEA agreement are presumed to be compatible with this measure. The application of this measure is subject to Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State from 19 April 2020.”*

In this regard, in order to reduce the risk of technical regulations raising regulatory barriers to trade, the Commission consistently points out the importance of introducing the “single market clause” into draft technical regulations laying down rules in non-harmonised or non-exhaustively harmonised areas.

The corollary to this acceptance of products from the rest of the European Union - extended by the Agreement on the European Economic Area to products from EFTA countries signatory to the Agreement<sup>10</sup> - is mutual recognition of the regulations relating to the design, manufacture and testing of products, and the conformity assessment procedures used; the Member States and the Commission are informed about these regulations through the procedure for the provision of information established by Directive (EU) 2015/1535.

Furthermore, the provisions of Decision 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union<sup>11</sup>, which provides for the elimination of quantitative restrictions or measures having equivalent effect between the EU and Turkey, are interpreted for the purposes of their implementation and application to products covered by the Customs Union, in conformity with the relevant decisions of the CJEU concerning provisions of the TFEU, in particular Articles 34 to 36 thereof.

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<sup>8</sup> Available at <https://ec.europa.eu/transparency/regdoc/rep/1/2017/EN/COM-2017-787-F1-EN-MAIN-PART-1.PDF>, see Section 3.

<sup>9</sup> Furthermore, at the specific request of the European Parliament, recital 16 of the newly adopted Regulation on mutual recognition (Regulation 2019/515) encourages Member States to use systematically the single market clause in their technical rules.

<sup>10</sup> It must be pointed out that the relevant provisions of the Agreement on the European Economic Area apply only to “products originating in the Contracting Parties” and not, consequently, to products simply marketed there.

<sup>11</sup> OJ L 35, 13.2.1996, p. 1.



Directive 98/34/EC, by extending the scope of application of the information procedure to rules on Information Society services, ensured, since August 1999, the prevention of new barriers to the freedom of establishment and the free movement of Information Society services by providing a mechanism to analyse the compatibility of new national legislation in this field with Articles 49, 56 TFEU and with the secondary legislation.

According to the case law of the CJEU, Articles 49 and 56 of the TFEU require the elimination of restrictions, i.e. of all "*measures which prohibit, impede or render less attractive the exercise of such freedoms*" (freedom of establishment and freedom to provide services).<sup>12</sup>

To be admissible as an exception to the fundamental freedoms of the internal market in a non-harmonised area, a national restriction must, on the basis of the case law, be justified, i.e. suitable, necessary and proportionate to the public objective pursued.<sup>13</sup> As regards the freedom to provide services, in particular, this means that national regulations which make no allowance for requirements already met by an operator in his Member State of establishment, from which he offers his services<sup>14</sup> will prove to be a disproportionate restriction and therefore inadmissible under Union law where the service in question is provided, as in the case of information society services, without the provider having to enter the territory of the Member State in which the service is received.<sup>15</sup>

Therefore, when examining national draft rules in the field of Information Society services, the Commission's overriding objective has been, for example, to oppose any national regulatory approach aimed at applying blanket, extra-territorial legal arrangements which make no distinction between operators based in the notifying Member State and those wishing to provide services in such Member State without, however, being established there. The Commission has also made sure that planned national rules do not impose needless or excessive legal or administrative costs on operators and possibly on users.

In order to enable the Directive to be fully effective, all the players - national authorities and the economic operators of the European Union - need to have a thorough understanding of its provisions and so be precisely aware of their rights and obligations.

This is all the more important since the CJEU, in April 1996, established the principle that failure to comply with the notification obligation results in the technical regulations concerned being inapplicable, so that they are unenforceable against individuals.<sup>16</sup> This case law, which has been confirmed on several occasions by the CJEU<sup>17</sup>, has also been applied to technical regulations adopted in breach of the standstill period.<sup>18</sup>

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<sup>12</sup> Case C-439/99 *Commission v Italy* EU:C:2002:14.

<sup>13</sup> Case C-76/90 *Dennemeyer* EU:C:1991:331; Case C-55/94 *Gebhard* EU:C:1995:411 and Case C-369/96 *Arblade* EU:C:1999:575.

<sup>14</sup> See *Arblade* judgment cited above, footnote 13.

<sup>15</sup> See *Dennemeyer* judgment cited above, footnote 13.

<sup>16</sup> Case C-194/94 *CIA Security* EU:C:1996:172.

<sup>17</sup> Case C-443/98 *Unilever* EU:C:2000:496; Case C-159/00 *Sapod Audic* EU:C:2002:343; Case C-26/11 *Belgische Petroleum Unie and Others* EU:C:2013:44; Case C-336/14 *Ince* EU:C:2016:72; Case C-285/15 *Beca Engineering* EU:C:2016:295; Case C-144/16 *Município de Palmela* EU:C:2017:76; Case C-299/17 *VG Media* EU:C:2019:716.

<sup>18</sup> Case C-443/98 *Unilever* EU:C:2000:496; Case C-95/14, *UNIC and Uni.co.pel* EU:C:2015:492.

The aim of this booklet is to inform all the actors - and particularly Europe's manufacturers and information society services providers - of the objectives, content and scope of a key instrument of the European Union for the removal at source of technical barriers to the free movement of goods, to the freedom of establishment and the freedom to provide Information Society services in the Single Market.

## CHAPTER I: THE SCOPE OF THE DIRECTIVE

Article 1 defines the meaning given by the Directive to a number of key terms, used throughout its provisions. This terminological and semantic clarification is essential to an effective understanding of the text and simultaneously defines the scope of the Directive.

### The scope of the Directive

#### *“Article 1*

*1. For the purposes of this Directive, the following definitions shall apply:*

*(a) ‘product’ means any industrially manufactured product and any agricultural product, including fish products;”*

The scope of the initial version of the Directive (i.e. 83/189/EEC) excluded cosmetic products within the terms of Directive 76/768/EEC<sup>19</sup>, medicinal products within the terms of Directive 65/65/EEC<sup>20</sup>, products destined for human and animal consumption and agricultural products, within the meaning of Article 38(1) TFEU.

The scope of the Directive has been extended, since the operation of the information procedure revealed that numerous national regulations and standards involving barriers to intra-EU trade had not been monitored by the Commission and the Member States because certain products were not covered.

In order to clarify the very broad definition which is now used for goods, it is worth recalling that the CJEU included in the framework of the provisions relating to the free movement of goods under Article 34 TFEU, “*products which can be valued in monetary terms and which may, as such, form the subject of commercial transactions*”.<sup>21</sup> In this context, the Court also ruled that waste, whether recyclable or not, is to be considered a product whose movement should not, in principle, be prevented.<sup>22</sup> It is appropriate to take this into consideration in determining the scope of the Directive.

*“(b) “service” means any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services*<sup>23</sup>.

*For the purposes of this definition:*

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<sup>19</sup> Repealed by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)

<sup>20</sup> Repealed by Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use. (OJ L 311, 28.11.2001, p. 67).

<sup>21</sup> Case 7/68 *Commission v Italy* EU:C:1968:51.

<sup>22</sup> Case 2/90 *Commission v Belgium* EU:C:1992:310.

<sup>23</sup> The notion of Information Society services was introduced by Directive 98/48/EC and then used in Directive 98/84/EC on the legal protection of services based on, or consisting of, conditional access (OJ L 320, 28.11.1998, p. 54) and Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (OJ L 178, 17.7.2000, p. 1).

(i) *"at a distance" means that the service is provided without the parties being simultaneously present,*

(ii) *"by electronic means" means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,*

(iii) *"at the individual request of a recipient of services" means that the service is provided through the transmission of data on individual request.*

*An indicative list of services not covered by this definition is set out in Annex I."*

It should be emphasised that the inclusion of Information Society Services was a very important extension of the scope of the Directive, which has brought it in line with new developments in international commerce.

According to the case law of the CJEU, the above mentioned four conditions laid down in Article 1(1)(b) of Directive 2015/1535 to consider an activity as an information society service ('any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services') are cumulative<sup>24</sup>.

To determine whether an activity comes within the definition of Information Society services, it is first necessary to verify whether the activity in question constitutes a "service" in accordance with Union law.

The Court has stipulated that the *"essential characteristic of remuneration [...] lies in the fact that it constitutes consideration for the service in question"*.<sup>25</sup> Such a characteristic is lacking in the activities the State undertakes without consideration within the framework of its tasks, particularly in social, cultural, educational and judicial fields. For this reason, Recital 19 of Directive 98/48/EC concluded that *"national provisions concerning such activities are not covered by the definition given in Article 60 [now Article 57] of the Treaty and therefore do not fall within the scope of this Directive"*.

Nevertheless, concerning the definition of "remuneration" of services, the CJEU has recognised that the service does not need to be paid by those for whom it is performed.<sup>26</sup> For example, activities financed entirely by advertising are remunerated and therefore constitute services.

Next, it is necessary to verify whether the service is, in the terms of the Directive, an 'Information Society service'. In accordance with Article 1(1)(b) of the Directive, Information Society service means a service provided: *"at a distance"*, *"by electronic means"* and *"at the individual request of a recipient of services"*.

The concept of *"at a distance"* concerns situations in which the service is provided using distance communication techniques, which are therefore characterised by the fact that the parties (i.e. the service provider and the recipient) are not physically and simultaneously present.

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<sup>24</sup> Case C-390/18 *Airbnb Ireland* EU:C:2019:1112.

<sup>25</sup> Case C-109/92 *Wirth* EU:C:1993:916.

<sup>26</sup> Case C-352/85 *Bond van Adverteerders* EU:C:1988:196.

The expression “*by electronic means*” means services whose constituent elements are transmitted, conveyed and received within an electronic network. The service must be conveyed from its point of departure to its point of arrival by means of electronic (processing and storage) equipment and by telecommunications means.

Finally, the service must be provided via the transmission of data at an individual request. This constitutes the element of interactivity which characterises Information Society services and sets them apart from other services that are sent without a request from the recipient being necessary. For this reason, Article 1(2) specifies that the Directive does not apply to radio broadcasting services and to television broadcasting services covered by point (e) of Article 1(1) of Directive 2010/13/EU<sup>27</sup>.

Moreover, Annex I contains an indicative list of services not covered by the definition set up by Article 1(1)(b), organised in three categories. In particular, the first category concerns “*services not provided ‘at a distance’*”, since services provided in the physical presence of the provider and the recipient cannot be considered as Information Society service, in the meaning of the Directive, even if they involve the use of electronic devices. The second category is related to “*services not provided ‘by electronic means’*”, such as, for example, automatic cash or ticket dispensing machines or CD-ROMs. The third category gives examples of “*services not supplied ‘at the individual request of a recipient of services’*”, like television or radio broadcasting services.<sup>28</sup>

Examples of services covered by the Directive are general online information services (newspapers, databases etc.), distance monitoring activities, interactive teleshopping, electronic mail, online flight reservations, online professional services (access to databases, diagnostics etc.), online intermediation service intended to connect, for remuneration, potential guests with professional or non-professional hosts offering short-term accommodation<sup>29</sup>.

“(c) ‘*technical specification*’ means a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.

*The term ‘technical specification’ also covers production methods and processes used in respect of agricultural products as referred to in the second subparagraph of Article 38(1) of the Treaty on the Functioning of the European Union (TFEU), products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 2001/83/EC of the European Parliament and of the Council<sup>30</sup>, as well as production methods and processes relating to other products, where these have an effect on their characteristics;”*

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<sup>27</sup> Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 95, 15.4.2010, p. 1).

<sup>28</sup> In the *Mediakabel* judgment of 2 June 2005, Case C-89/04, EU:C:2005:348, the Court of Justice has confirmed that near video on demand is not an Information Society Services since it is not provided at a distance.

<sup>29</sup> Case C-390/18 *Airbnb Ireland* EU:C:2019:1112.

<sup>30</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

This provision defines the concept of technical specification, a generic term which covers standards as well as technical regulations.

It stipulates that the document containing the technical specification defines “*the characteristics required of a product*”. The examples given are not exhaustive: the composition of the product<sup>31</sup>, its shape, weight, packaging<sup>32</sup>, presentation<sup>33</sup>, performance, life span, energy consumption, etc., could have been added. A technical specification presupposes that the national measure prescribing it refers to the product or its packaging as such and that it therefore lays down one of the characteristics required of that product<sup>34 35</sup>.

The specification may serve a multitude of goals: for example, protection of the consumer, of the environment, public health or safety, standardisation of production, improvement of quality, fairness of commercial transactions, maintenance of public order. Such specifications, however, should not be introduced for goods without a firm justification: serving a legitimate public interest that is objective and being proportionate.

The initial version of the Directive limited the definition of technical specification to the characteristics required of the product. The broadening of the concept of technical specification to include production processes and methods was carried out in two stages: firstly in 1988 (by Directive 88/182/EEC<sup>36</sup>) with regard to agricultural products, products for human and animal consumption and medicinal products, at the time of their inclusion in the scope of the Directive; secondly in 1994 (by Directive 94/10/EC<sup>37</sup>) with regard to other products, for the sake of consistency.

In the field of agriculture, products for human and animal consumption and medicinal products, production methods and processes generally affect the product itself (for example, the obligation to vaccinate cows before selling them<sup>38</sup>). This is not always the case in the other product sectors, and here the Directive makes impact on the product a condition of notification of the production methods and processes concerned, with the specific exclusion of regulations relating to the organisation of work, which does not affect products.

Testing and test methods, quoted as examples of technical specifications, cover the technical and scientific methods to be used to evaluate the characteristics of a given product. The conformity assessment procedures, which are also mentioned, are those used to ensure that the product conforms with specific requirements. They are the responsibility of specialist bodies, whether public or private, or of the manufacturer.

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<sup>31</sup> Case C-303/04 *Lidl Italia* EU:C:2005:528.

<sup>32</sup> Case C-159/00 *Sapod Audic* EU:C:2002:343.

<sup>33</sup> Case C-20/05 *Schwibbert* EU:C:2007:652.

<sup>34</sup> In Case C-727/17 *ECO-WIND Construction* EU:C:2020:393, the Court ruled that a legislation which merely regulates the installation of wind turbines by laying down a mandatory minimum distance requirement that must be complied with for their installation does not refer to a product as such, in this case the wind generator, and, therefore, does not lay down one of the characteristics required of that product within the meaning of the Directive.

<sup>35</sup> Case C-711/19, *Admiral Sportwetten and Others*, EU:C:2020:812.

<sup>36</sup> Council Directive 88/182/EEC of 22 March 1988 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 81, 26.3.1988, p. 75).

<sup>37</sup> Directive 94/10/EC of the European Parliament and of the Council of 23 March 1994 materially amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 100, 19.4.1994, p. 30).

<sup>38</sup> Case C-37/99 *Donkersteeg* EU:C:2000:636.

The inclusion of these parameters within the scope of the Directive is of the utmost importance, because testing and conformity assessment procedures can, under certain conditions, have negative effects on trade. The multiplicity and disparity of the national systems of conformity certification can cause technical barriers to trade in the same way as the specifications applicable to the products, which are even more difficult to overcome as a result of their complexity.

*“(d) ‘other requirement’ means a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;”*

The concept of “*other requirement*”, as defined by this paragraph, did not exist in the initial version of Directive 83/189/EEC. It was introduced by Directive 94/10/EC, at the time of the second amendment of the text.

This term covers requirements which do not represent technical specifications but conditions that have an effect on the life cycle of a product, from the period of marketing to the phase of management or disposal of the waste generated by it.

The provision specifies that this type of requirement is principally imposed for the purpose of protecting consumers or the environment. These are two of the grounds of major legitimate public interest objectives which could, in exceptional circumstances, justify a Member State departing from the principle of the free movement of goods by imposing trading bans or restrictions.

The “*conditions of use, recycling, reuse or disposal of a product*”, quoted as examples of “*other requirements*”, refer to the most important specific cases. In order to qualify as “*other requirements*”, these conditions must be likely to have a significant effect on the composition, the nature or the marketing of the product.<sup>39</sup> A decree relating to the management of medicinal waste or a national regulation seeking to impose a return or reuse system for packaging, or even the separate collection of certain products, such as discharged batteries, can therefore be expected to contain provisions which fall into the category of “*other requirements*”.

*“(e) ‘rule on services’ means a requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point (b), in particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point.*

*For the purposes of this definition:*

*(i) a rule shall be considered to be specifically aimed at Information Society services where, having regard to its statement of reasons and its operative part, the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner;*

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<sup>39</sup> Case C-303/15 *M. and S.* EU:C:2016:771, Case C-98/14 *Berlington* EU:C:2015:386, Joined cases C-213/11, C-214/11 and C-217/11 *Fortuna and Others* EU:C:2012:495, Case C-65/05 *Commission v Greece* EU:C:2006:673, Case C-267/03 *Lindberg* EU:C:2005:246, Case C-137/17 *Van Gennip and Others* EU:C:2018:771, Case C-727/17 *ECO-WIND Construction* EU:C:2020:393.

*(ii) a rule shall not be considered to be specifically aimed at Information Society services if it affects such services only in an implicit or incidental manner.”*

Examples of measures likely to constitute a rule on Information Society services include measures concerning the conditions for taking up an activity (e.g. rules on the establishment of service providers<sup>40</sup>, in particular those on authorisation or licensing arrangements<sup>41</sup>); measures relating to the conditions for pursuing an on-line activity (e.g. general ban on commercial promotion or certain forms of advertising, registration requirements, prohibition to publish certain types of information<sup>42</sup>); measures concerning the provider of on-line services (e.g. requirements relating to professional experience required to be an on-line tax consultant); measures concerning the supply of on-line services (e.g. laws laying down the maximum fees which may be charged, mandatory insurance or reporting obligations) and measures related to the recipient of such services (e.g. participation limited to certain age group, measures applying to specific categories of recipients, such as minors); and well as the extension of the exclusive right to operate certain games of chance awarded to a public entity for the entire national territory to operations on the internet<sup>43</sup>.

It is extremely important to emphasise that the obligation to notify in advance does not apply to all draft national regulations which - directly or indirectly, explicitly or implicitly - may concern Information Society services. Only a limited number and a well-defined category of draft national regulations will, for the purposes of the Directive, have to be notified in advance, namely the regulations specifically aimed at Information Society services. All other regulations affecting services are not notifiable.

In view of the above, one should point out that the Directive requires the notification of regulatory drafts whose justification, content or purpose<sup>44</sup> indicate that they are directly and openly devoted, in whole or in part, to regulating Information Society services. The provision(s) in a national regulatory instrument must be expressly drafted or in any event specifically designed to reflect the fact that the activity/service is supplied “*at a distance, by electronic means and at the individual request of a recipient of services*”.

Another point which should be emphasised is that it is not solely regulatory instruments which *as a whole* are devoted to Information Society services (e.g. a law on electronic signatures) that must be notified. Regulations *of which only a part* (possibly an article or even a paragraph) specifically concerns an Information Society service (e.g. within a law on pornography, a specific provision on the liability of an Internet access supplier) must also be notified.<sup>45</sup>

A provision is to be considered as “specifically aimed at information society services having regard to both its statement of reasons and its operative part” if it pursues that aim or object in some of its provisions. Even where it is not apparent solely from the wording of a national rule that it is aimed, at least in part, at regulating information society services specifically, that object may be gleaned from the stated reasons given for the rule, as they appear, in accordance with the

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<sup>40</sup> In Case C-255/16 *Falbert* EU:C:2017:983, the CJEU clarified that “National provisions that merely lay down the conditions governing the establishment or provisions of services by undertakings, such as provisions making the exercise of a business activity subject to prior authorization do not constitute technical regulations”.

<sup>41</sup> See Recital 18 of Directive 98/48/EC.

<sup>42</sup> Case C-299/17 *VG Media* EU:C:2019:716.

<sup>43</sup> Case C-275/19 *Sportingbet and Internet Opportunity Entertainment* EU:C:2020:856.

<sup>44</sup> Case C-255/16 *Falbert*, judgment cited above, footnote 41.

<sup>45</sup> See Recitals 17 and 18 of Directive 98/48/EC.



relevant national rules of interpretation in that regard, *inter alia* from the ‘travaux préparatoires’ for the rule.<sup>46</sup>

On the other hand, there is no need to notify those technical regulations that relate only indirectly, implicitly or incidentally to Information Society services, i.e. which concern an economic activity in general without taking into consideration the typical technical procedures for supplying the Information Society services (e.g. a provision which prohibits the distribution of paedophile material by any means of transmission, including the Internet or electronic mail, among the various possible means of dissemination or a provision applicable to an intermediation service that is provided by means of a smartphone application and forms an integral part of an overall service the principal element of which is the transport service<sup>47</sup>). Similarly, a national measure which makes no mention of the information society and applies to all kinds of ‘dispatching’ service without distinction, whether provided by telephone or by IT application, cannot be considered as specifically aimed at information society services and, in consequence, should not be considered as technical regulations<sup>48</sup>.

*“(3) This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of telecommunications services covered by Directive 2002/21/EC”.*<sup>49</sup>

Directive 90/387/EEC<sup>50</sup> (repealed by Directive 2002/21/EC) defined telecommunications services as *“services whose provision consists wholly or partly in the transmission and routing of signals on a telecommunications network by means of telecommunications processes, with the exception of radio broadcasting and television”*.

The reason for this specific exemption is that in the field of telecommunications services (as in financial services, see following section) a large number of matters are already harmonised and are part of an already existing and sufficiently defined regulatory framework at the EU level.

*“(4) This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of financial services, as listed non-exhaustively in Annex II to this Directive.”*

The reason for such an exemption from the scope of the Directive is identical to the previous one, and is due to the fact that such rules are part of an already sufficiently established Union legal framework.

For pure guidance purposes, a non-exhaustive list of financial services is supplied in Annex II to Directive (EU) 2015/1535.

*“(5) With the exception of Article 5(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 2004/39/EC or by or for other markets or bodies carrying out clearing or settlement functions for those markets.”*

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<sup>46</sup> Case C-299/17 *VG Media* EU:C:2019:716.

<sup>47</sup> See judgement in case C-320/16 *Uber France* EU:C:2018:221.

<sup>48</sup> Case C-62/19 *Star Taxi app* EU:C:2020:980.

<sup>49</sup> See footnote 25.

<sup>50</sup> Council Directive 90/387/EEC of 28 June 1990 on the establishment of the internal market for telecommunications services through the implementation of open network provision (OJ L 192, 24.7.1990, p. 1).

Directive 2004/39/EC of 21 April 2004 regulates trading activities on financial markets and enhances investor protection.<sup>51</sup>

As a result of this exemption, the rules drawn up by or concerning regulated markets or other markets or bodies carrying out clearing or settlement operations for such markets are not subject to the obligation of prior notification. The only obligation to which such rules are subject, in the interests of minimal transparency, is that of “ex-post” notification, i.e. they should be communicated to the Commission after adoption at national level pursuant to Article 5(3), which - as indicated in Article 1, point 5 - is the only provision in the Directive which applies to these rules.

“(f) ‘technical regulation’ means technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 7, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider”.

In defining the concept of ‘technical regulation’, paragraph (f) provides information regarding the type of texts which must be notified under the procedure for the provision of information established by the Directive in this field.

On the one hand, there are the ‘technical specifications’ and ‘other requirements’ or ‘rules on services’ (see the above definitions), which are laid down by the Member States and which are applicable to industrial and agricultural products and to Information Society services, and, on the other, there are ‘the laws, regulations and administrative provisions of the Member States which prohibit certain specified activities’.

In order to qualify as a *technical regulation*, a ‘technical specification’, an ‘other requirement’ or ‘a rule on services’ must fulfil the following conditions:

- it must be ‘compulsory’ (i.e. *de jure* or *de facto* binding, see hereinafter). This characteristic, which is inherent in the documents prepared by the public authorities, to which this Directive applies, constitutes the major difference between a *technical regulation* and a *standard*, which is prepared by private bodies and is in essence voluntary;<sup>52</sup>
- it must influence the marketing or use of industrial and agricultural products, the provision of a service or the establishment of a service operator, in a Member State or a significant part of that State.

The administrative provisions applicable to a specification, to an ‘other requirement’ or to a ‘rule on services’ can also constitute technical regulations within the meaning of the Directive. These measures, as with all technical regulations, must be notified under the Directive when they emanate

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<sup>51</sup> Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments (OJ L 145, 30.4.2004, p. 1) has been repealed by Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments (JO L 173 du 12.6.2014, p. 349) with effect from 3 January 2018.

<sup>52</sup> However, in certain cases, compliance with the standard may become mandatory, so that it then acquires the status of a ‘technical regulation’.

from the central governments of the Member States or from one of their authorities as specified in the list drawn up by the Commission in the framework of the Standing Committee of the Directive<sup>53</sup>  
54.

Certain technical specifications, ‘other requirements’ or rules on services which meet the definition of technical regulations are excluded from the scope of the Directive, particularly if they merely comply with binding Union acts<sup>55</sup> or are limited to implementing a judgment of the Court of Justice of the European Union, as specified in Article 7 of the Directive.

The ‘compulsory’ nature of a technical specification, an ‘other requirement’ or a rule on services may be conferred upon them in two ways:

1. *de jure*, when compliance with them is made compulsory by a measure emanating directly from the relevant public authorities or is attributable to the latter.

By way of example, the conditions regarding the small-scale production of jam and preserved fruit, laid down by decree, will be considered to be a technical regulation which is mandatory *de jure*. The same will apply to a ban on using plastic bottles for the marketing of mineral water, as laid down by ordinance, etc.

2. *de facto*, where the technical specification is not laid down by a formal and binding act of the State concerned, but where the State encourages its observance. As a result of the similar effects which they may have upon trade, these measures are considered equivalent to binding regulations.

Paragraph (f) gives three examples of the most important and the most frequent *de facto* technical regulations, in order to clarify a concept which was not defined in the initial version of the Directive and gave rise to different interpretations that were prejudicial to the correct implementation of the information procedure.

*“De facto technical regulations include:*

*(i) laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or other requirements or to rules on services, compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions;”*

The laws, regulations or administrative provisions referred to are measures adopted by the national authorities which refer to technical specifications or ‘other requirements’<sup>56</sup> or to rules on services usually laid down by bodies other than the State (by a national standardisation body), which are not compulsory as such (for example, standards, professional codes or codes of practice), but observance of which is encouraged since it confers on the product or the service a presumption of conformity with the provisions of the aforementioned measures.

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<sup>53</sup> Case C-62/19 *Star Taxi app* EU:C:2020:980.

<sup>54</sup> List of authorities required to notify draft technical regulations (in addition to the central governments of the Member States) (Article 1, point 11 of Directive 98/34/EC) (OJ C 127, 31.5.2006, p. 14).

<sup>55</sup> Case C-390/99 *Canal Satélite Digital* EU:C:2002:34; Case C-443/98 *Unilever* EU:C:2000:496.

<sup>56</sup> In the meaning of Article 1(c) and (d) of the Directive, as explained above.

Such is the case, in particular, if a law relating to insurance releases the users of products complying with certain non-mandatory standards from the responsibility of proving conformity with mandatory requirements, since these products benefit from a presumption of conformity with the requirements.

*“(ii) voluntary agreements to which a public authority is a contracting party and which provide, in the public interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications;”*

Agreements entered into between economic operators which establish technical specifications or other requirements for certain products or rules on services are not binding as such owing to their origin in the private sector. They are nevertheless considered to be *de facto* technical regulations when the State is a signatory party to one of these agreements.

This circumstance is becoming increasingly frequent, since such agreements have become instruments of national regulatory policy. They are often used by some Member States in sectors such as the automobile industry, chemical industry and oil industry, in most cases for environmental reasons. For example to reduce pollutant vehicle emissions, the discharge of harmful substances into water, or the use of certain types of packaging, etc. In the field of Information Society services, a notified text -a draft Code of Practice on voluntary retention of communication data- provides a good example of such voluntary agreement.

These agreements allow greater flexibility in implementing the measures necessary to attain the objectives of the legislation, and the voluntary participation of the industry involved ensures that they will be achieved.

The State must be involved in these agreements if they are to fall within the scope of Directive (EU) 2015/1535. For the public authority to be able to fulfil the information obligation incumbent on it and take account of comments by the Commission or a Member State in the framework of the information procedure laid down by the Directive, the State must be a contracting party.

*“(iii) technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services linked to national social security systems are not included.”*

The fiscal or financial measures referred to in this paragraph are laid down by the national public authorities for a purpose other than that traditionally pursued by the fiscal legislation of the Member States.

They are considered to be efficient instruments for implementing policies decided at a national level, particularly with a view to protecting the environment and the recipients of services (notably the consumers), since they are basically aimed at influencing the behaviour of the latter with regard to a specific product or service.

This provision of the Directive came about because of certain cases of tax incentives granted to ‘clean vehicles’ which met certain emission limits or were equipped with catalytic converters. Experience has shown that Member States often linked incentives to conditions, with the result that the system introduced was contrary to Union law. It became clear that there was a need to examine such drafts as well.

The category of measures in question includes, in particular, those which seek to encourage the purchase of products complying with certain specifications, by granting financing facilities (for example, subsidies for the purchase of certain heating appliances complying with defined technical requirements) or, alternatively, to discourage their purchase (for example the exclusion of grants in the building industry when materials possessing certain characteristics are used). It also includes fiscal or financial measures which may affect consumption by encouraging compliance with “other requirements” within the meaning of the Directive (for example, exemption from ecotax for the packaging of given products when a deposit system is set up, or exemption from ecotax for certain products when a collection and recycling system is established). Similarly, this category of measures concern those aiming at encouraging or discouraging the purchase of services having certain features (e.g. services received via specific devices or originating from operators established in certain areas).

Directive (EU) 2015/1535 does not cover the whole of the fiscal or financial legislation of the Member States; it only refers to ‘technical specifications’, ‘other requirements’ or rules on services linked to fiscal or financial measures which have the objective of changing the behaviour of consumers or service recipients<sup>57</sup>. The fiscal or financial measure does not, as such, form the subject of examination by the Commission or the Member States. The assessment of the measure, by the Commission and the other Member States, is limited to the technical specifications or other requirements or rules on services that it contains, and their comments or detailed opinions may concern only aspects that may hinder trade or, as regards rules on services, the free movement of services or the freedom of establishment of services operators. The drafts concerned also benefit from special treatment with regard to the standstill periods (see Article 7(4)), as no standstill period is laid down for the adoption of these texts by Member States (see Chapter II, Section III below).

It should be emphasised that draft legislation which contains ‘fiscal or financial measures’ within the meaning of Directive (EU) 2015/1535 must be notified under this Directive, even if the measures concerned constitute as well State aid within the meaning of Article 107(1) TFEU, in which case they must also be notified to the Commission pursuant to Article 108(3) TFEU, before such measures are put into effect.

Measures connected with the national social security systems are also excluded (for example the regulation which makes the refund of a medicine conditional on a certain type of packaging).

National laws, regulations and administrative provisions intended to prohibit the manufacture, importation, marketing and use of a product or, for Information Society Services, prohibiting the provision or use of a service or the establishment as a service provider are considered to be technical regulations for the purpose of the notification obligation under the Directive (EU) 2015/1535, in addition to the technical specifications, the ‘other requirements’ and the rules on services which impose *de jure* and *de facto* compulsory requirements.

To fall within this fourth category of technical regulation concerning a prohibition *inter alia* on use, the measures must have a scope which goes well beyond a limitation to certain possible uses of the product or the service in question and must not be confined to a mere restriction of their use. That category of technical regulation is particularly intended to cover national measures which leave no

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<sup>57</sup> Case C-711/19, *Admiral Sportwetten and Others*, EU:C:2020:812.

room for any use which can reasonably be made of the product concerned other than a purely marginal one.<sup>58 59</sup>

Such prohibitions constitute, as it were, the ultimate form of technical regulation. Unless they can be justified under Article 36 or Article 52 TFEU or are proportionate in relation to essential requirements within the terms of the case law of the CJEU, they constitute barriers *par excellence* to the free movement of goods and services and to the freedom of establishment within the Union<sup>60</sup>.

*“This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list drawn up and updated, where appropriate, by the Commission, in the framework of the Committee referred to in Article 2.*

*The same procedure shall be used for amending this list;”*

The list of authorities referred to in this paragraph has been published in the Official Journal of the European Union.<sup>61</sup>

*“(g) ‘draft technical regulation’, the text of a technical specification or other requirement or of a rule on services, including administrative provisions formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made.”*

This paragraph defines the concept of “draft technical regulation”: in order to be considered a draft, the technical regulation must be at a stage of preparation which will enable “substantial amendments” to be made to the text.

The procedure for the provision of information laid down by the Directive in the field of technical regulations provides that, on completion of the examination of drafts which it has been sent, the Commission and the Member States can request the regulatory authority to amend any text which is considered to be contrary to the rules of the internal market.

It is a matter for each Member State to decide, in accordance with its legislative process, the stage at which its draft technical regulations should be sent to the Commission, as long as it is still possible to make substantial amendments.

In that regard, it must be observed that a national measure which reproduces or replaces, without adding new or additional specifications, existing technical regulations which, if adopted after the entry into force of Directive 83/189/EEC, have been duly notified to the Commission, cannot be regarded as a ‘draft’ technical regulation within the meaning of Article 1(g) of Directive (EU) 2015/1535 and consequently, as subject to the obligation to notify.<sup>62</sup>

Paragraphs 2 to 6 of Article 1 of the Directive include the following exceptions:

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<sup>58</sup> Case C-267/03 *Lindberg* EU:C:2005:246, and Case C-144/16 *Município de Palmela* EU:C:2017:76.

<sup>59</sup> Case C-727/17 *ECO-WIND Construction* EU:C:2020:393.

<sup>60</sup> Case C-303/04 *Lidl Italia* EU:C:2005:528.

<sup>61</sup> List of authorities required to notify draft technical regulations (in addition to the central governments of the Member States) (Article 1, point 11 of Directive 98/34/EC) (OJ C 127, 31.4.2006, p. 14).

<sup>62</sup> Case C-33/97 *Colim* judgment of 3 June 1999, EU:C:1999:274, paragraph 22.

*“2. This Directive shall not apply to:*

*(a) radio broadcasting services;*

*(b) television broadcasting services covered by point (e) of Article 1(1) of Directive 2010/13/EU of the European Parliament and of the Council<sup>63</sup>.*

*3. This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of telecommunications services, as covered by Directive 2002/21/EC of the European Parliament and of the Council<sup>64</sup>.”*

Directive 2002/21/EC defines electronic communications service as *“a service normally provided for remuneration which consists wholly or mainly in the conveyance of signals on electronic communications networks, including telecommunications services and transmission services in networks used for broadcasting, but exclude services providing, or exercising editorial control over, content transmitted using electronic communications networks and services; it does not include information society services, as defined in Article 1 of Directive 98/34/EC, which do not consist wholly or mainly in the conveyance of signals on electronic communications networks;”*.

*“4. This Directive shall not apply to rules relating to matters which are covered by Union legislation in the field of financial services, as listed non-exhaustively in Annex II to this Directive.”*

The reason for such an exemption from the scope of the Directive is identical to the aforementioned and is due to the fact that such rules are part of an already sufficiently established European Union legal framework.

Purely as guidance, a non-exhaustive list of financial services is supplied in Annex II to Directive (EU) 2015/1535.

*“5. With the exception of Article 5(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 2004/39/EC of the European Parliament and of the Council <sup>65</sup> or by or for other markets or bodies carrying out clearing or settlement functions for those markets.”*

As a result of this exemption, the rules drawn up by or concerning regulated markets or other markets or bodies carrying out clearing or settlement operations for such markets are not subject to the obligation of prior notification. The only obligation to which such rules, in the interests of minimal transparency, are subject is that of “ex-post” notification, i.e. they should be communicated to the Commission after adoption at national level pursuant to Article 5(3),

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<sup>63</sup> Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media service (Audiovisual Media Services Directive) (OJ L 95, 15.4.2010, p. 1).

<sup>64</sup> See footnote 25.

<sup>65</sup> Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments (OJ L 145, 30.4.2004, p. 1), repealed since 2.1.2018 by Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (OJ L 173, 12.6.2014, p. 349).

which - as indicated by the fourth subparagraph of Article 1, point 5 - is the only provision in the Directive which applies to these rules.

*“6. This Directive shall not apply to those measures Member States consider necessary under the Treaties for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.”*

This provision reinforces a concept already expressed in paragraphs (c) and (d) of Article 1(1) of the Directive, to the effect that technical specifications which affect the characteristics of the product are covered.



## CHAPTER II: THE PROCEDURE APPLICABLE TO TECHNICAL REGULATIONS

### **I. The communication and distribution of information on draft technical regulations and the possible reactions open to the Commission and the Member States**

#### *“Article 5*

*1. Subject to Article 7, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these grounds have not already been made clear in the draft.*

*Where appropriate, and unless it has already been sent with a prior communication, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned to the Commission, should knowledge of such text be necessary to assess the implications of the draft technical regulation.*

*Member States shall communicate the draft technical regulation again to the Commission under the conditions set out in the first and second subparagraphs of this paragraph if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.*

*Where, in particular, the draft technical regulation seeks to limit the marketing or use of a chemical substance, preparation or product on grounds of public health or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the principles provided for in the relevant part of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>66</sup>.*

*The Commission shall immediately notify the other Member States of the draft technical regulation and all documents which have been forwarded to it; it may also refer this draft, for an opinion, to the Committee referred to in Article 2 of this Directive and, where appropriate, to the committee responsible for the field in question.*

*With respect to the technical specifications or other requirements or rules on services referred to in point (iii) of the second subparagraph of point (f) of Article 1(1), the comments or detailed opinions of the Commission or Member States may concern only aspects which may hinder trade, or, in*

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<sup>66</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

*respect of rules on services, the free movement of services or the freedom of establishment of service operators, and not the fiscal or financial aspect of the measure.*

*2. The Commission and the Member States may make comments to the Member State which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.*

*3. Member States shall communicate the definitive text of a technical regulation to the Commission without delay.*

*4. Information supplied under this Article shall not be confidential except at the express request of the notifying Member State. Any such request shall be supported by reasons.*

*In cases of that kind, if the necessary precautions are taken, the Committee referred to in Article 2 and the national authorities may seek expert advice from physical or legal persons in the private sector.*

*5. When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Union act, Member States may make a communication within the meaning of paragraph 1 under that other act, provided that they formally indicate that the said communication also constitutes a communication for the purposes of this Directive.*

*The absence of a reaction from the Commission under this Directive to a draft technical regulation shall not prejudice any decision which might be taken under other Union acts.”*

Article 5 lists the obligations of the Member States and the Commission respectively under the procedure for the provision of information in the field of technical regulations, and the possible reactions open to them, apart from reactions relating to standstill periods to be respected before the adoption of the notified drafts, which are referred to in Article 6 of the Directive.

### ***First stage: the obligation to inform***

#### **a) The Member States' obligations**

##### ***1. General rules***

In order to guarantee the transparency of national initiatives, Article 5 of the Directive requires the Member States to communicate immediately to the Commission any draft technical regulation which they plan to adopt.

The full text of the draft act containing the draft technical regulation must be sent.<sup>67</sup> However, only technical regulations are subject to the standstill obligation.

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<sup>67</sup> Case C-279/94 *Commission v Italy* EU:C:1996:396; Case C-336/14 *Ince* EU:C:2016:72; Case C-144/16 *Município de Palmela* EU:C:2017:76.

Moreover, when the draft involves the incorporation in full of an international or European standard into internal law, the Member State may make reference to the standard rather than communicate the full text.<sup>68</sup>

At the time of the notification, the notifying Member State must also send the text of the basic legislative and regulatory provisions to the Commission, to provide the legal context of the notified draft and to facilitate its assessment (for example, in the event the notified draft amends a basic text)<sup>69</sup>. If these basic legislative and regulatory provisions are not sent, the Commission can request them on receipt of the draft.

This obligation is coupled with an obligation to notify the grounds justifying the enactment of the proposed measures.<sup>70</sup>

In order to facilitate the understanding and the analysis of the draft, it is also recommended that Member States provide any additional legal or economic information underpinning the justification and the impact of the adoption of the proposed technical regulation (impact assessment, statistics, economic data related to the market of the sector concerned, etc).

Each Member State designates a central coordinating point responsible for the notification of draft technical regulations to the Commission and for the coordination with the line ministries at national level (a list of these central coordinating points, so called ‘contact points’, can be consulted on the web page: <http://ec.europa.eu/growth/tools-databases/tris/en/contact/>).

In practice, the notification of a draft technical regulation to the Commission entails the submission of a notification message to the Commission.

This ‘notification message’ includes sixteen points, each of which corresponds to a specific information required. In point 16, for example, the notifying Member State must indicate whether the draft includes TBT (WTO Agreement on Technical Barriers to Trade) aspects or sanitary and phytosanitary (SPS) aspects.

After the adoption of the notified draft, the notifying Member State must send the definitive text of the technical regulation to the Commission (see Article 5(3) of the Directive). The Commission will thus be in a position to consider whether the Member State has aligned the text with Union law and, if appropriate, to take any necessary measures.

If the Member State has adopted the notified draft without taking account of the detailed opinion issued by the Commission or the other Member States on the draft technical regulation, the Commission can initiate an infringement procedure according to Article 258 TFEU.<sup>71</sup>

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<sup>68</sup> This reference enables the Commission, and the Member States which wish to do so, to obtain without difficulty the text of the standard which has been made compulsory.

<sup>69</sup> Case C-145/97 *Commission v Belgium* EU:C:1998:212.

<sup>70</sup> An examination of the grounds presented shows that they most often relate to the protection of persons or animals, the environment, public safety, or to consumer information.

<sup>71</sup> Article 258 TFEU (ex Article 226) provides that “[i]f the Commission considers that a Member State has failed to fulfil an obligation under the Treaties, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations. If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice of the European Union.”

The Member States themselves can bring the matter before the Commission, under Article 259 of the TFEU, in order to initiate infringement proceedings before the CJEU against a Member State which they consider to have failed to fulfil its obligations.<sup>72</sup>

## 2. *Specific cases*

### 2.1. *Single notification valid for multiple Union acts.*

In parallel to the notification procedure set up by Directive (EU) 2015/1535, a number of other EU legislative acts provide for a notification obligation. In order to facilitate the task of the Member States and of the Commission in the event of overlapping notification procedures, i.e. where several Union acts require the Member State to notify the same text at the draft stage, a ‘one-stop-shop’ procedure has been established.

Member States can notify only once, but they must indicate, at the time of the notification (under point 7 of the notification message), all specific Union acts under which the notification of the draft shall also be considered valid.

Following the official communication that the notification is valid for several EU procedures, the national draft is thus examined on its own merits on the basis of each Union act to which it refers, and is the subject of a Commission opinion under each procedure.

This is why the absence of a Commission reaction to such a draft text under Directive (EU) 2015/1535 ‘shall not prejudice any decision which might be taken under other Union acts’ (see the second subparagraph of Article 5(5)).

2.2. *Basic legislation already sent.* With the same concern for efficiency, Member States are exempt from the obligation to send the text of the basic legislative and regulatory provisions concerning a draft technical regulation to the Commission, if this text has already been sent with a prior communication.

This is the case, for example, when the draft technical regulation is aimed to amend a technical regulation previously notified.

The notifying Member State must indicate, in point 10 of the notification message, the references and the notification numbers of the basic texts.

2.3. *Additional documentation.* Conversely, the Directive provides for an obligation for Member States with regard to draft technical regulations designed to limit the marketing or use of a chemical

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<sup>72</sup> Article 259 TFEU (ex Article 227) provides that “[a] Member State which considers that another Member State has failed to fulfil an obligation under the Treaties may bring the matter before the Court of Justice of the European Union. Before a Member State brings an action against another Member State for an alleged infringement of an obligation under the Treaties, it shall bring the matter before the Commission.

The Commission shall deliver a reasoned opinion after each of the States concerned has been given the opportunity to submit its own case and its observations on the other party’s case both orally and in writing.

If the Commission has not delivered an opinion within three months of the date on which the matter was brought before it, the absence of such opinion shall not prevent the matter from being brought before the Court”.

substance, preparation or product for reasons of public health, the protection of consumers or the environment (c.f. fourth subparagraph of Article 5(1)).

For such drafts Member States must provide a summary of or references to all the relevant facts available on the chemical substance, preparation or product concerned and any known substitute, the foreseeable effects of the measure, and the results of the risk analysis.

In this respect, the Directive specifies that the analysis must be carried out in accordance with the general principles laid down in the REACH Regulation.<sup>73</sup>

**2.4. New notification.** Member States must notify again a draft which has already been examined under the provisions of the Directive, if they have made significant amendments to the text in the meantime.

The third subparagraph of Article 5(1) specifies that amendments made to the text are considered to be significant if they have the effect of altering its scope, shortening the timetable originally envisaged for its implementation<sup>74</sup>, adding specifications or requirements<sup>75</sup>, or making the latter more restrictive.

It should be emphasised that notification is not necessary in the case of a simple restatement of provisions which are already applicable (for example, in the event of consolidation), and which are without legal effect or, of course, in the cases provided for by Article 7 of the Directive (e.g. integration in the text of remarks made by the Commission in a detailed opinion<sup>76</sup>, see hereinafter).

## **b) The obligations of the Commission**

When the Commission has been notified of a new draft national technical regulation, it must transmit all the information communicated by the notifying Member State to all the other Member States (fifth subparagraph of Article 5(1) of the Directive).

This communication of information enables all the Member States to be fully involved in the monitoring procedure laid down by the Directive.

The Commission also places the notified drafts and their translations on its website<sup>77</sup>, which offers all the economic operators in the single market the opportunity to take note of and to express their views on draft national legislation, except where, under Article 5(4) of the Directive, the notifying Member State expressly requests that the information communicated to the Commission should

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<sup>73</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

<sup>74</sup> In Case C-307/13 *Ivansson and Others*, EU:C:2014:2058, the Court stated that the date finally chosen by the national authorities for the entry into force of a national measure is subject to the obligation of communication to the Commission, as laid down in the third subparagraph of Article 8(1) of Directive 98/34 (now Article 5(1) of Directive (EU) 2015/1535) where a change to the timetable for the implementation of that national measure was, in effect, made, and was significant in nature, which it is for the national court to ascertain..

<sup>75</sup> Case C-317/92 *Commission v Germany*, EU:C:1994:212.

<sup>76</sup> Case C-26/11 *Belgische Petroleum Unie and Others* EU:C:2013:44.

<sup>77</sup> <http://ec.europa.eu/growth/tools-databases/tris>

exceptionally be treated as confidential with regard to economic operators and provides a justification for such a request.

The confidentiality, granted by Article 5(4) of the Directive, of notified draft technical regulations should be invoked exceptionally, since it derogates from the principle of transparency. The Commission carefully monitors Member States' use of confidential notifications under Article 5(4) of the Directive and takes the necessary measures in case of suspected abuse of that provision.<sup>78</sup> As required by Article 5(4) of the Directive, such requests must be justified. The Commission includes these reasons on the TRIS database. Moreover, certain basic information about the notified measure are always made available on the TRIS database, such as the title of the measure.

The Directive allows the Commission to submit the draft to the Standing Committee or “*to the committee responsible for the field in question*” for an opinion (fifth subparagraph of Article 5(1) of the Directive). The latter are committees which cover sectoral directives, like the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM), established by Directive 99/5/EC<sup>79</sup> for the radio equipment.

In practice, the Commission is responsible for managing the procedure for the provision of information in the field of technical regulations. The whole procedure, including the reactions to the notified drafts, is based on a system of electronic data exchange, transmitted in accordance with a nomenclature set up by the Commission.

The Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs acts as the central point for the receipt of all messages, texts and notifications communicated by the Member States, regardless of the field of the draft regulation (mechanical engineering, food and agricultural products, transport, construction products, Information Society services etc.). Following reception, the notified draft is simultaneously communicated to all Commission departments which may be concerned by the notified measure according to their specific or horizontal responsibilities.

The draft which is circulated under the procedure is also dispatched by the Commission to all Member States, firstly in the language of the notifying Member State and then in the form of translations into all or some of the official languages of the Union (upon request and depending on the length of the draft).

### ***Second stage: possible reactions from the Commission and the Member States***

During the three months following the notification of a draft (this period corresponds to the standstill period referred to in Article 6(1)), the Commission and the Member States examine the notified draft text in order to assess its compatibility with the EU law, particularly with Articles 34 and 36, 49 and 56 TFEU, but also with the sectoral secondary legislation involved, and to reach a decision, where necessary, on its consistency with the concerned provisions.

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<sup>78</sup> See, in respect, Decision of the Ombudsman in case 2204/2018/TE.

<sup>79</sup> Directive 99/5/EC of the European Parliament and Council of 9 March 1999 relating to radio and telecommunications terminal equipment, including the mutual recognition of their conformity, OJ L 91, 7.4.1999, p.1, repealed by Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (OJ L 153, 22.5.2014, p. 62).

The results of this evaluation can give rise to two types of reaction by the Commission and the Member States (the Commission has, in addition, a specific option: the postponement of the adoption of the draft as a result of harmonisation work, which will be examined below in the comments on Article 6 of the Directive). The various reactions are as follows:

1. The Commission and/or the Member States can decide that the draft technical regulation is not of a nature to form barriers to the free movement of goods, to the free provision of information society services and to the freedom of establishment of service operators.

In this case, neither the Commission nor the Member States react during the three-month period.<sup>80</sup> At the end of this period, the notifying Member State can adopt its draft technical regulation, without any further obligations other than to communicate the definitive text of the technical regulation (Article 5(3) of the Directive) to the Commission.

However, this right does not exclude a subsequent intervention by the Commission, outside the procedure under Directive (EU) 2015/1535, if the regulation as finally adopted should prove to be contrary to the TFEU or to secondary EU legislation.

2. The Commission and the Member States can send comments or a detailed opinion to the Member State that notified the draft technical regulation.

EU Member States participate in this procedure on an equal footing with the Commission. They can issue comments and detailed opinions on any notified draft technical regulations.

Comments are sent, for examples, when the notified text, although in accordance with the EU law, raises issues of interpretation or calls for details of the arrangements for its implementation. They can also give an overall assessment of the measure, having regard to the general principles of EU law and policies implemented in this context, or inform the Member State of its future obligations with regard to acts to be adopted on at EU level.

The Directive stipulates that the Member States shall take comments into account “*as far as possible*” (Article 5(2)). Member States do, however, generally take account of the comments they receive.

Under the Directive, the notifying Member State has no formal obligation to reply to the comments received. In practice, Member States sometimes do so on a voluntary basis.

Detailed opinions (mentioned later, together with their consequences, in Article 6 of the Directive) are sent by the Commission or the Member States when they consider that the draft measure envisaged would, if adopted, create obstacles to the free movement of goods, the freedom to provide Information Society services or the freedom of establishment of the above service operators within the Internal Market. These detailed opinions seek to obtain an amendment to the proposed measure, in order to remove at source any resulting barriers to such freedoms, and have the effect of extending the standstill period for three (for products) or one (for Information Society services) additional months.

These issues relate to the illegality of the draft in terms of Union law, through a breach of Articles 34, 49 or 56 of the TFEU or of secondary EU legislation. The most frequent breaches detected in

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<sup>80</sup> Although it is not sent to the notifying Member State, the decision not to follow up the notification is a formal decision by the Commission.

the framework of the notification procedure concern national rules contrary to Articles 34, 49 or 56 TFEU or/and to the main provisions of secondary EU law related to free movement of goods or Information Society services, notably because some of the provisions of the draft are not necessary or disproportionate in relation to the pursued objective, in breach of the requirement laid down by the CJEU with respect to the exceptions to the fundamental freedoms of the internal market in a non-harmonised area.

A detailed opinion may not, under any circumstances, be issued against draft regulations which impose manufacturing prohibitions but do not constitute a potential barrier to the free movement of goods (Article 7(2) of the Directive).

Member States shall reply to detailed opinions addressed to them by the Commission or another Member States. In particular, the Member State to which such an opinion is addressed must inform the Commission or the other Member States of the actions it intends to take (withdrawal of the disputed text, justification for retaining it, or the amendment of certain provisions in order to render them compatible with the rules of the internal market).

Although the Directive does not specify the time allowed for replying, it is nevertheless desirable that a response is provided as soon as possible in the interests of efficiency, preferably during the standstill periods of six or four months, respectively for goods and Information society services.

The Commission shall comment, in turn, on the actions envisaged by the Member State in response to its detailed opinion, in order to let the Member State know whether these measures are suited to eliminate the barriers to the free movement of goods, the free provision of Information Society services or the freedom of establishment of the above service operators which may have resulted from the adoption of the text, or whether the justification given for retaining the text is acceptable.

If the Commission considers that the reply to its detailed opinion is unsatisfactory, it can initiate, if the draft is actually adopted without the necessary amendments, the procedure referred to in Article 258 TFEU. Similarly, a Member State has the right, in the event of adoption of the notified draft by another Member State without complying with EU law, to institute the infringement proceedings provided for by Article 259 TFEU.

With regard to technical specifications, 'other requirements' or rules on services linked to fiscal or financial measures, the last subparagraph of Article 5(1) of Directive (EU) 2015/1535 provides that the comments and detailed opinions can only relate to aspects which may create barriers to the free movement of goods or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators, and not to the fiscal or financial aspects of the measure. The Member States' fiscal powers are thus not under scrutiny in this respect. These drafts also benefit from special treatment with regard to the standstill periods (see Article 7(4)), as no standstill period is laid down for the adoption of these texts by Member States.

3. The Commission can announce an EU harmonisation initiative on the subject of the proposed national measure or its finding that such an initiative exists. The consequences of this reaction, which is for the exclusive use of the Commission, are described in Article 6(3), (4) and (5) of the Directive (see below).

## **II. The obligation to observe the standstill period**



## **“Article 6**

1. *Member States shall postpone the adoption of a draft technical regulation for three months from the date of receipt by the Commission of the communication referred to in Article 5(1).*

2. *Member States shall postpone :*

- *for four months the adoption of a draft technical regulation in the form of a voluntary agreement within the meaning of point (ii) of the second subparagraph of point f of Article 1(1).*
- *without prejudice to paragraphs 3, 4 and 5 of this article, for six months the adoption of any other draft technical regulation (except for draft rules on services,*

*from the date of receipt by the Commission of the communication referred to in Article 5(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of goods within the internal market,*

- *without prejudice to paragraphs 4 and 5, for four months the adoption of any draft rule on services, from the date of receipt by the Commission of the communication referred to in Article 5(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of services or to the freedom of establishment of service operators within the internal market.*

*With regard to draft rules on services, detailed opinions from the Commission or Member States may not affect any cultural policy measures, in particular in the audiovisual sphere, which Member States might adopt in accordance with the law of the Union, taking into account of their linguistic diversity, their specific national and regional characteristics and their cultural heritage.*

*The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.*

*With respect to rules on services, the Member States concerned shall indicate, where appropriate, the reasons why the detailed opinions cannot be taken into account.”*

Article 6 concerns the timing of the notification procedure. The date of receipt by the Commission of the draft national technical regulation communicated by a Member State and of all the requested documents is the signal for the beginning of a period of time during which the Member State concerned is strictly obliged not to adopt the draft at issue.

This period of time is known as the standstill period.

The three-month period referred to in Article 6(1) is the initial standstill period. It represents the period that is considered necessary in order to allow the Commission and the other Member States to examine the notified draft text and to react to it, if necessary.<sup>81</sup>

In addition to this period, an additional standstill period may be triggered and its length depends on the nature of the notified text and the type of reaction by the Commission or the other Member States. Whereas comments sent to the Member State do not extend the initial three-month standstill period, the same does not apply to detailed opinions sent by the Commission or the other Member States.

In the event of a detailed opinion relating to a voluntary agreement or to draft rules on Information Society services, the Directive stipulates that the Member States must respect a standstill period of four months (Article 6(2)). It adds only one month to the initial standstill period.

The standstill period is extended to six months for all other drafts which are the subject of a detailed opinion.

### **The postponement of the adoption of the draft:**

*“Article 6*

[...]

*3. With the exclusion of draft rules relating to services, Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 5(1) of this Directive if, within three months of that date, the Commission announces its intention to propose or adopt a directive, regulation or decision on the matter in accordance with Article 288 TFEU.*

*4. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 5(1) of this Directive if, within the three months following that date, the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the European Parliament and the Council in accordance with Article 288 TFEU.*

*5. If the Council adopts a position at first reading during the standstill period referred to in paragraphs 3 and 4, that period shall, subject to paragraph 6, be extended to 18 months.”*

Paragraphs 3, 4 and 5 of Article 6 stipulate much longer standstill periods as a result of the postponement imposed by the Commission - and by the Commission alone - following examination of the draft. The Member State shall delay the adoption of the draft for 12 or 18 months if EU harmonisation work is to be undertaken or is already underway in the same field.

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<sup>81</sup> With the exception of : a) urgent cases, b) laws, regulations or administrative provisions by Member States prohibiting manufacture, as long as these do not form barriers to the free movement of goods (see Article 7(2)), c) technical specifications or other requirements linked with financial or fiscal measures (see Article 7(4)).

This reaction, the most serious consequence for the Member States in terms of time, is intended to prevent the notified draft from adversely affecting a legislative harmonisation process which has commenced at Union level.

The postponement of the adoption of a draft national regulation can be imposed by the Commission in three specific cases:

1. Paragraph 3 covers the first case: the Commission announces its intention to propose or adopt a directive, regulation or decision (in other words any of the binding Union acts under Article 288 of the TFEU) on the same subject as the text of the draft technical regulation.

This paragraph does not specify what is meant by ‘the intention’ to propose, but it concerns an intention that has been explicitly expressed, for example through inclusion in the Commission’s annual legislative programme.

Member States must then respect a standstill period of 12 months.

In the field of Information Society Services, the Commission cannot require the postponement of the adoption of a draft simply by stating its intention to propose or adopt a binding Union act relating to the subject of the text. The fact that the Commission is in the process of drafting a Union act is not sufficient to justify a standstill period of 12 months for the Member State concerned.

2. In the second case (paragraph 4), the Commission finds that the notified draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the European Parliament and to the Council.

In this case, as in the preceding case, the notifying Member State must respect a standstill period of 12 months. Contrary to the preceding case, this effect applies also in the field of Information Society Services.

3. Paragraph 5 envisages the third specific case, when the Council adopts a common position during the twelve-month postponement imposed in the two previous situations. In this case, the Directive stipulates that the standstill period imposed on the Member State is extended to 18 months.

It should be emphasised that the ‘common position’ referred to in this paragraph represents a stage of the Union legislative process under the ordinary legislative procedure (previously called co-decision)<sup>82</sup>. This procedure provides for a second reading of the text by the European Parliament when the Council amends the European Parliament’s position, which explains the need to extend the standstill period.

*“6. The obligations referred to in paragraphs 3, 4 and 5 shall lapse:*

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<sup>82</sup> Introduced by the by the Maastricht Treaty in 1992, its use was extended in 1999. With the adoption of the Lisbon Treaty, co-decision was renamed the ordinary legislative procedure and it became the main decision-making procedure used for adopting EU legislation (Articles 289 and 294 TFEU).

- (a) *when the Commission informs the Member States that it no longer intends to propose or adopt a binding Union act;*
- (b) *when the Commission informs the Member States of the withdrawal of its draft or proposal;*
- (c) *when a binding act has been adopted by the European Parliament and the Council or by the Commission.”*

Paragraph 6 concerns the expiry of the standstill period imposed on the Member State in the event the adoption of a draft technical regulation is postponed by the Commission.

Since the length of the process that will lead to the final approval of Union legislation is uncertain, the Commission uses this instrument with caution.

It is logical that, where an action which is envisaged or in progress at Union level does not produce a result, the standstill obligations imposed by paragraphs 3, 4 and 5 should lapse in order to allow the Member States to complete the postponed legislative work at a national level and to adopt the technical regulation.

These standstill obligations also lapse when the Council and the Parliament adopt, or when the Commission adopts, the announced binding Union act.

***The Urgency procedure:***

*“Article 6*

*[...]*

*7. Paragraphs 1 to 5 shall not apply in cases where:*

*(a) for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants, and for rules on services, also for public policy, in particular the protection of minors, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible; or*

*(b) for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, in particular the protection of depositors, investors and insured persons, a Member State is obliged to enact and implement rules on financial services immediately.*

*In the communication referred to in Article 5, the Member State shall give the reasons for the urgency of the measures taken. The Commission shall give its views on the communication as soon as possible. It shall take appropriate action in cases where improper use is made of this procedure. The European Parliament shall be kept informed by the Commission.”*

This paragraph provides that the standstill periods are not applicable when a Member State, in order to respond to an urgent, serious and unforeseeable situation such as, for example, a natural disaster (the need to protect people, the atmosphere, soil or water), an epidemic, etc., is obliged to prepare

technical regulations for immediate adoption, without having time to consult the Commission and the other Member States beforehand. This is the case, for instance, when a Member State regulates the control or the ban of new types of narcotics drugs, psychotropic substances, medicinal products, or takes measure to fight against terrorism.

Concerning rules on services, Member States can invoke the urgency clause also for urgent reasons occasioned by serious and unforeseeable circumstances relating to public policy, notably the protection of minors. This concept reflects the special importance attached by the Union legislator to the protection of minors in the context of Information society services. The urgency request was accepted, for example, for draft measures concerning the protection of internet users from websites inciting or condoning acts of terrorism and websites disseminating illicit pornographic images, as well as for draft rules on the cooperation arrangement between service providers providing encrypted communication and national bodies authorised to gather secret information in the context of the so-called Islamic State's expansion.

The urgency clause may also be invoked, where rules relating to financial services are concerned, for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons. This special and less strict form of urgency clause is provided for exclusively in the field of Information Society financial services on account of certain risks and requirements specific to this sector.

These exceptional circumstances do not exempt the Member State from the obligation to notify the Commission of the planned measures and to clearly justify its request for urgency at the time when the draft text is communicated. In point 12 of the notification message, the notifying Member State must indicate, on the basis of the limited criteria and public interest mentioned in the Directive for the urgency, the reasons why it cannot wait for the three-month standstill period for adopting the draft technical regulation.

The Commission has to assess whether the use of the urgency procedure is justified and to give its views on the communication as quickly as possible.

In practice, the Commission carries out a very thorough analysis of the reasons given, on the basis of the two criteria contained in Article 6(7), i.e. the seriousness of the situation and (apart from financial services) its unforeseeable nature, taking into account the public interest mentioned in this Article. The two criteria (seriousness and unforeseeability) are cumulative. The urgent adoption shall be necessary, depending on the case, for the protection of public health or safety, the protection of animals or the preservation of plants, and for rules on services, also for public policy, in particular the protection of minors, the protection of the security and the integrity of the financial system, in particular the protection of depositors, investors and insured persons.

If the Commission considers that these criteria are not met, it rejects the urgency request and the standstill period starts from the date of the notification. Conversely, the Commission may accept the application of this procedure.

By way of illustration, neither the deadline to transpose a directive nor proceedings before the CJEU can be considered as unforeseeable circumstances in the sense of Article 6(7) of the Directive. The urgency procedure is also refused when the justification is based on purely economic grounds or the political agenda before elections. It is important to remind that Article 6(7) of the Directive

constitutes an exemption from the Member States' obligation to comply with the standstill periods provided for in Article 6(1) to (5). As such, it is subject to a strict interpretation.<sup>83</sup>

The decision on the urgency procedure does not prejudice the Commission's assessment of the technical regulation on the merits, namely its analysis of whether the notified draft or the measure adopted is compatible with EU law.

In the event of adoption of measures in relation to which the request for urgency has been rejected, without observance of the standstill period, the Commission can launch the infringement procedure referred to in Article 258 of the TFEU against the Member State concerned for breach of the obligations provided for by the Directive.

### **III. Exceptions to the obligation to notify and to observe standstill periods**

#### *Article 7*

This Article supplements Articles 5 and 6 of the Directive, by stating the exceptions to the obligation to notify a draft national technical regulation. It also provides for certain exceptions to the obligation to comply with the standstill periods stipulated in Article 6.

*“1. Articles 5 and 6 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements by means of which Member States:*

- (a) comply with binding Union acts which result in the adoption of technical specifications or rules on services;*
- (b) fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Union;”*

The limits to this exception can best be illustrated with reference to the fundamental objective of the Directive, which is the elimination of unjustified trade barriers.

If the Member States adopt the same set of rules as required by a Union act, trade barriers and differences between national laws are removed at the same time, and the procedure laid down by the Directive is no longer needed.

This reasoning is the same with regard to international agreements: when such an agreement contains precise provisions and there is no scope for divergence, the adoption by all Member States of a uniform set of rules is not, in principle, likely to result in trade barriers. This exemption applies in relation to international agreements to which all Member States are signatory.

The situation is different when the Union act or the international agreement is implemented through measures which may differ from one Member State to another, or when uniform provisions, which have to be transposed, are supplemented by rules which are of purely national origin.

Several judgments have clarified the scope of the exception laid down in point (a) of Article 7(1) of Directive (EU) 2015/1535, whereby Member States are not obliged to notify texts by means of

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<sup>83</sup> Judgments of the CJEU of 26 October 2006 in Case C-65/05 *Commission v Hellenic Republic* EU:C:2006:673 and of 10 July 2014 in Case C-307/13 *Ivansson and Others* EU:C:2014:2058.

which they comply with binding EU acts which result in the adoption of technical specifications or rules on Information Society services.

In 1996<sup>84</sup>, the Court recalled that there must be a direct link between a binding Union act and the national measure in order to qualify the latter as an implementing measure exempt from the notification requirement under Article 10 of Directive 83/189/EEC (now point (a) of Article 7(1) of Directive (EU) 2015/1535).

In 1999, in joined cases *Albers, Van den Berkmortel and Nuchelmans*<sup>85</sup>, the Court considered that in issuing the prohibition on administering Clenbuterol to fattening cattle, the Netherlands honoured its obligations under Directive 86/469/EEC concerning the examination of animals and fresh meat for the presence of residues, and that the technical regulation was therefore exempt, under Article 10 of Directive 83/189/EEC (now Article 7 of Directive (EU) 2015/1535), from the duty of notification.

Conversely, the Court specified, in the *Unilever* judgment<sup>86</sup>, that Article 10 of Directive 98/34/EC (now Article 7 of Directive (EU) 2015/1535) may not be invoked when a provision of a directive allows the Member State sufficient room for manoeuvre. This was the case in point. Italy had asserted that Council Directive 79/112/EEC on the labelling of foodstuffs imposed the obligation to include in the labelling particulars of the place of origin or provenance of the product in cases where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff. According to the Court, this provision is drafted in general terms and leaves sufficient room for manoeuvre. Therefore, national rules on labelling relating to the origin of olive oil cannot be regarded as national provisions conforming to a binding Community act within the meaning of the first indent of Article 10(1) of Directive 98/34/EC (now point (a) of Article 7(1) of Directive (EU) 2015/1535).

This restrictive interpretation of point (a) of Article 7(1) of the Directive was confirmed by the Court in the *Canal Satélite Digital* judgment<sup>87</sup>. In this judgment, the Court reiterated that Article 10 of Directive 98/34/EC (now Article 7 of Directive (EU) 2015/1535) shows that the obligation to notify and to observe the standstill period does not apply to laws, regulations or administrative provisions of Member States, or to voluntary agreements by means of which Member States comply with binding Union measures which result in the adoption of technical specifications. To the extent that the national measure at issue in the main proceedings transposed Directive 95/47/EC on the use of standards for the transmission of television signals, and to that extent only, there would be no obligation to notify under Directive 98/34/EC (now Directive (EU) 2015/1535). However, having regard to the content of Directive 95/47/EC, the Court considered that the national legislation in question, in so far as it established a system of prior administrative authorisation, - which in fact is not provided for by Directive 95/47/EC - could not be qualified as legislation whereby the Member State complies with a binding Community measure resulting in the adoption of technical specifications.

The same reasoning applies to measures adopted to conform with an international agreement which contains specific provisions for the implementation of which no possibility of divergence is laid down. Measures adopted to conform with an agreement to which all the Member States are

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<sup>84</sup> Case C-289/94 *Commission v Italy* EU:C:1996:330.

<sup>85</sup> Case C-425/97 *Albers*, Case C-426/97 *Van den Berkmortel*, Case C-427/97 *Nuchelmans* EU:C:1999:243.

<sup>86</sup> Case C-443/98 *Unilever* EU:C:2000:496.

<sup>87</sup> Case C-390/99 *Canal Satélite Digital* EU:C:2002:34.

party come within this exception; if these are measures adopted to conform with an international agreement to which not *all* the Member States are party, they must be notified.

*“(c) make use of safeguard clauses provided for in binding Union acts;”*

Member States do not have to notify the Commission, under Directive (EU) 2015/1535, of the draft provisional measures which are authorised to take under the safeguard clause contained in EU Directives, in accordance with Article 114 TFEU. This Article lays down in paragraph 10 that *“The harmonisation measures (...) shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure”*.

These non-economic reasons can relate to public morality, public order or public security, the protection of the health and life of humans, animals or plants, the protection of national treasures possessing artistic or archaeological value or the protection of industrial and commercial property.

*“(d) apply Article 12(1) of Directive 2001/95/EC”;*<sup>88</sup>

Member States do not have to notify, under Directive (EU) 2015/1535, draft national technical regulations relating to the application of Article 12(1) of the Directive on general product safety.

This Article provides that *“where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX<sup>89</sup>. It shall also inform the Commission without delay of modification or withdrawal of any such measure or action (...)”*.

*“(e) restrict themselves to implementing a judgment of the Court of Justice of the European Union;”*

Member States do not have to notify national measures which have the sole objective of implementing a judgment of the CJEU relating to an aspect other than the notification of a technical regulation. Judgments by this Court, which is responsible for ensuring compliance with Union law, must be enforced immediately.

*“(f) restrict themselves to amending a technical regulation within the meaning of point (f) of Article 1(1), in accordance with a Commission request, with a view to removing an obstacle to*

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<sup>88</sup> Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p.4).

<sup>89</sup> RAPEX, whose legal basis is Directive 2001/95/EC on General Product Safety, serves as a single rapid alert system for dangerous consumer products. All non-food products intended for consumers or likely under reasonably foreseeable conditions to be used by consumers are included within the scope of RAPEX, with the exception of pharmaceutical and medical products.



*trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.”*

Member States are not required to notify national measures aimed solely at amending a technical regulation in order to remove obstacles in response to a request, for instance through a detailed opinion or comments, from the Commission, since these measures are precisely in accordance with the objective of Directive (EU) 2015/1535.<sup>90</sup>

*“2. Article 6 shall not apply to the laws, regulations and administrative provisions of the Member States prohibiting manufacture insofar as they do not impede the free movement of products.”*

Under the terms of this paragraph, a standstill period does not apply to measures seeking to prohibit manufacturing, to the extent that these do not obstruct the free movement of goods within the Union. In this case, it is obvious that postponement of the adoption of measures only makes sense if the manufacturing prohibitions present a potential risk of constituting a technical barrier to trade in the internal market.

*“3. Paragraphs 3 to 6 of Article 6 shall not apply to the voluntary agreements referred to in point (ii) of the second subparagraph of point (f) of Article 1(1).”*

Under the terms of this paragraph, the postponement and the standstill obligations applicable to draft national regulations concerning a subject covered by current or imminent legislative work at Union level do not apply to voluntary agreements.

### **Fiscal or financial measures**

*“4. Article 6 shall not apply to the technical specifications or other requirements or the rules on services referred to in point (iii) of the second subparagraph of point (f) of Article 1(1).”*

As far as draft technical regulations concerning fiscal or financial measures are concerned, it was considered inopportune to apply the standstill obligations to measures linked to the fiscal system of the Member States.

However, the absence of the standstill obligation for the notifying Member State does not exclude the Commission or another Member State can react to these drafts by means of comments or detailed opinions (See Article 7(4)).

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It may be concluded from the reading of Articles 5, 6 and 7 of Directive (EU) 2015/1535 that the information procedure applicable to technical regulations is quite complex. The guidelines produced by the Commission departments, and distributed to the national contact points, explain in detail how

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<sup>90</sup> Case C-26/11 *Belgische Petroleum Unie and Others* EU:C:2013:44.

the procedure operates in practice (ex.: Practical guidelines on the definition and notification of ‘fiscal or financial measures’ for the purposes of Directive (EU) 2015/1535, or Guidelines on the management of urgency procedures pursuant to Article 6(7) of Directive (EU) 2015/1535).

Furthermore, the provisions of the Directive on technical regulations impose very strict obligations on the Member States, which are balanced by the right to react to draft national regulations being prepared by other Member States and by the possibility to save time for much more complex procedures, both at Union and national levels, which would result from *ex post* procedures purely limited at removing already existing regulatory obstacles.

Where the Member States fail to meet their obligation to communicate their draft technical regulations to the Commission, or do not observe the standstill periods laid down in the Directive, the Commission can institute infringement proceedings, under Article 258 TFEU, as already mentioned. When the Member State concerned does not comply with EU law, the procedure can lead to a judgment for failure to fulfil obligations by the CJEU.<sup>91</sup>

Private individuals can, for their part, rely on the fact that technical regulations with which they are required to comply, but which have not been notified, cannot be enforced against them.<sup>92</sup> Furthermore, in the *Unilever* judgment, the CJEU concluded that a measure that has been notified but subsequently adopted during the standstill period laid down in Article 6 of Directive (EU) 2015/1535, cannot be enforced against individuals.<sup>93</sup>

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<sup>91</sup> Reference to these judgments is made in Point III of the bibliography.

<sup>92</sup> Case C-194/94 *CIA Security* EU:C:1996:172; Case C-226/97 *Lemmens* EU:C:1998:296; Case C-26/11 *Belgische Petroleum Unie and Others* EU:C:2013:44; Case C-285/15 *Beca Engineering* EU:C:2016:295 and Case C-336/14 *Ince* EU:C:2016:72; Case C-299/17 *VG Media*, EU:C:2019:716.

<sup>93</sup> Case C-443/98 *Unilever* EU:C:2000:496 and Case C-95/14 *Unic and Uni.co.pel* EU:C:2015:492.

### CHAPTER III: THE PROCEDURE FOR THE PROVISION OF INFORMATION WITH REGARD TO STANDARDS

The European standardisation having been the subject to a specific regulation<sup>94</sup> since 1 January 2013, the standardisation section has been removed from Directive 98/34/EC<sup>95</sup>, with the exception of the current Article 4 of Directive (EU) 2015/1535 (ex Article 7(2), second paragraph, of Directive 98/34/EC).

#### ***“Article 4***

*Member States shall communicate to the Commission, in accordance with Article 5(1), all requests made to standards institutions to draw up technical specifications or a standard for specific products for the purpose of enacting a technical regulation for such products in the form of draft technical regulations, and shall state the grounds for their enactment.”*

Standards are defined as technical specifications, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory.

This article concerns specific cases in which the national standards are to be made compulsory by Member States via technical regulations.

Indeed, in order to enforce the observance of standards which are essentially voluntary, a Member State may use two procedures:

- it may make existing standards compulsory, and in doing so, transform them into technical regulations;
- it can also request its country’s standardisation body to prepare standards in view of establishing technical regulations.

Article 4 provides for an obligation, for Member States, to notify the Commission of requests addressed to national standardisation bodies to draw up technical regulations (first case) or a national standard (second case) for specific products for the purpose of enacting a technical regulation.

The reason for this obligation is simple: national standards becoming partly or as a complement of a national technical regulation could act as barriers to the proper functioning of the internal market.

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<sup>94</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation (OJ L 316, 14.11.2012, p. 12).

<sup>95</sup> In Case T-229/17 *Germany v Commission* EU:T:2019:236, the General Court of the EU confirmed that Regulation (EU) No 1025/2012 removed from Directive 98/34/EC all provisions related to the European harmonisation procedure.

## CHAPTER IV : THE STANDING COMMITTEE

### *“Article 2*

*A Standing Committee shall be set up consisting of representatives appointed by the Member States who may call on the assistance of experts or advisers; its chairman shall be a representative of the Commission.*

*The Committee shall draw up its own rules of procedure.*

### *Article 3*

*1. The Committee shall meet at least twice a year.*

*The Committee shall meet in a specific composition to examine questions concerning Information Society services.*

*2. The Commission shall submit to the Committee a report on the implementation and application of the procedures set out in this Directive, and shall present proposals aimed at eliminating existing or foreseeable barriers to trade.*

*3. The Committee shall express its opinion on the communications and proposals referred to in paragraph 2 and may, in that regard, propose, in particular, that the Commission:*

*(a) ensure where necessary, in order to avoid the risk of barriers to trade, that initially the Member States concerned decide amongst themselves on appropriate measures;*

*(b) take all appropriate measures;*

*(c) identify the areas where harmonisation appears necessary, and, should the case arise, undertake appropriate harmonisation in a given sector.*

*4. The Committee must be consulted by the Commission:*

*(a) when deciding on the actual system through which the exchange of information provided for in this Directive is to be effected and on any change to it;*

*(b) when reviewing the operation of the system provided for in this Directive.*

*5. The Committee may be consulted by the Commission on any preliminary draft technical regulation received by the latter.*

*6. Any question regarding the implementation of this Directive may be submitted to the Committee at the request of its Chairman or of a Member State.*

*7. The proceedings of the Committee and the information to be submitted to it shall be confidential.*

*However, the Committee and the national authorities may, provided that the necessary precautions are taken, consult, for an expert opinion, natural or legal persons, including persons in the private sector.*

*8. With respect to rules on services, the Commission and the Committee may consult natural or legal persons from industry or academia, and where possible representative bodies, capable of delivering an expert opinion on the social and societal aims and consequences of any draft rule on services, and take note of their advice whenever requested to do so.”*

Articles 2 and 3 describe the composition and role of the Standing Committee.

The Committee is composed of representatives of the Member States' national authorities and chaired by a representative of the Commission. It has competence for technical regulations and constitutes the focal point for discussion of all issues connected with the implementation of the Directive. It therefore plays a very important role in supervising the operation of the procedure and in the examination of policy issues raised by the notifications and also in developing an administrative network between national authorities.

The operating rules of this body have been agreed by the Member States and the Commission, since the Directive stipulates that the Committee shall draw up its own rules of procedure. The only rules imposed by the Directive on the Standing Committee are the obligation to meet at least twice per year, and to guarantee the confidential nature of both the information submitted to it and of its proceedings.

This duty of discretion does not, however, prevent the Committee and the national authorities from using the expertise of natural persons or legal entities in the private sector, who are capable of examining and forming an opinion on the notified drafts. This advice can in fact be indispensable, since the national authorities of the Member States do not always have the necessary knowledge and resources to carry out this task. The Directive makes this possible unless, in accordance with Article 5(4), the Member States expressly request that notifications which they have carried out be treated confidentially as an exception. In this case, the Committee must take the necessary precautions in order to safeguard the legitimate and duly justified interests of the Member States.

In practice, the Standing Committee meets twice per year. These meetings are convened by the Commission.

The meetings of the Standing Committee enable the Commission departments and the Member States to exchange views on all aspects of the application of the Directive.

In the framework of these meetings, any question relating to the implementation of the Directive can be brought before the Standing Committee at the request of its Chairman or of a Member State.

In addition, it must be consulted by the Commission on certain points, including the choice of the system to be used in practice for the exchange of information laid down by the Directive.

The Committee expresses an opinion on proposals presented by the Commission in order to limit existing or potential trade barriers: it can, for example, ask the Commission to encourage dialogue between the Member States, so that they can find - in application of the subsidiarity principle - solutions between themselves. The encouragement of such dialogue is in accordance with the spirit of Directive (EU) 2015/1535 which seeks to remove barriers at source, by prevention rather than coercion.

Every two years, the Commission presents to the Committee the report which it will send to the European Parliament and the European Economic and Social Committee on the results of the application of the Directive (see Article 8).

The Standing Committee can specifically request the Commission to identify those areas in which harmonisation of national legislation is necessary and to begin work at a European level (the preparation of a proposal for a directive or a regulation).

It draws up a list of national authorities, other than central governments, whose technical regulations fall within the scope of the Directive and examines any draft amendment to the latter.

The Committee is also the forum for discussion of numerous issues, from technical problems encountered in the exchange of information by electronic mail, to the difficulties arising from the overlapping of the notification procedure under Directive (EU) 2015/1535 with the notification procedures provided for by other Union acts.

Apart from the meeting of the Standing Committee, meetings organised within the Member States, extend, where necessary, direct contacts between the representatives of the national authorities responsible for drafts technical regulations and the Commission departments.

These meetings also provide an opportunity for contacts with the representatives of the central units of the Member States responsible for the application of Directive (EU) 2015/1535, with a view to settling practical problems encountered in the application of the information procedure, finding solutions which will enable infringement proceedings launched by the Commission for non-notification of draft national regulations to be closed, or avoiding such proceedings.

## CHAPTER V - THE APPLICATION OF THE DIRECTIVE

### I. Reports and statistics

#### *“Article 8*

*The Commission shall report every two years to the European Parliament, the Council and the Economic and Social Committee on the results of the application of this Directive.*

*The Commission shall publish annual statistics on the notifications received in the Official Journal of the European Union.”*

This Article sets out the Commission’s obligations in respect of guaranteeing the transparency of information on the application of Directive (EU) 2015/1535, both as regards the institutions of the European Union and bodies representing the political and economic interests of the citizens of the Union, as well as the citizens themselves.

The reports which the Commission must submit to the European Parliament, the Council and the European Economic and Social Committee describe the operation of the Directive during the reference period.<sup>96</sup>

A specific report from the Commission to the European Parliament and the Council on the evaluation of the application of Directive 98/34/EC in the field of Information Society Services was published in 2003 to take stock of the situation as the Directive was extended to this sector in August 1999.<sup>97</sup>

### II. Reference to the Directive at the time of adoption of technical regulation

#### *“Article 9*

*When Member States adopt a technical regulation, it shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States.”*

This Article requires Member States to make reference to Directive (EU) 2015/1535 either in the text of the new technical regulations they adopt or as a supplement to the text at the time of its publication. The wording of this reference is left to the discretion of the Member States.

Although this reference is not an absolute guarantee of compliance by the Member State with the Directive, it does at least establish a presumption that the technical regulation has been duly notified.

This obligation is of fundamental importance for private individuals, who are authorised to assert their rights in the case of the adoption of a technical regulation without prior notification (see the case law referred to in the following Chapter VI).

### III. Timetable and Application Methods

Directive 83/189/EEC was adopted on 28 March 1983 and entered into force on 31 March 1984.

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<sup>96</sup> Reference is made to these judgments in Point I of the bibliography.

<sup>97</sup> COM(2003) 69 final, 13.2.2003.

It was first amended by Directive 88/182/EEC, which entered into force on 1 January 1989. The second amendment came into force on 30 June 1995 and was brought about by Directive 94/10/EC.

The procedure was then codified by Directive 98/34/EC of 22 June 1998 and modified by Directive 98/48/EC of 20 July 1998, mainly to extend its application to Information Society services. This extension came into force on 5 August 1999.

Directive 98/34/EC, as modified, was then codified and replaced by Directive (EU) 2015/1535 of 9 September 2015, which entered into force on 7 October 2015.

The manner in which these Directives were transposed was left, as for any other Directive, to the discretion of the Member States in accordance with Article 288 of the TFEU which states that “*A Directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods*”.<sup>98</sup>

Directive (EU) 2015/1535 is characterised by the fact that it contains a large number of procedural rules, which the Member States had to implement.

## **CHAPTER VI : ACCESS TO INFORMATION BY PRIVATE INDIVIDUALS AND INDUSTRY AND THEIR REACTION OPTIONS**

Although the implementation of Directive (EU) 2015/1535 is above all a matter for the parties involved in the procedure for the provision of information in the field of technical regulations - the Commission and Member States - information on draft technical regulations is of considerable interest to all citizens of the Union.

The Commission invites all economic operators, the real beneficiaries of the notification procedure, including all categories of recipients of Information Society services (companies, professionals, consumers, etc.), to inform themselves of all draft legislation and regulations being prepared by the Member States at a sufficiently early stage, in order to be able, should they so wish:

- to anticipate the adoption of future national technical regulations in other Member States, by adapting their production in order to comply with the precise content of these texts. In this way, manufacturers and services providers can, when the time comes, immediately provide products and services which comply fully with the requirements of these regulations;
- to express their views on necessary amendments to proposed technical regulations which may form barriers to trade, in order to facilitate the access to products and to Information Society services at cross-border level. Economic operators can submit their comments on difficulties which may arise from the application of the texts, once adopted, in their field.

This is invaluable information for the Commission departments, since they do not have equivalent practical experience of the relevant fields.

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<sup>98</sup> As opposed to a regulation which “shall be binding in its entirety” and “directly applicable in all Member States”.



These comments may be submitted directly via TRIS (Technical Regulations Information System)<sup>99</sup> (see below) or sent to the relevant Commission departments or to the national authorities responsible for administering Directive (EU) 2015/1535 in the field of technical regulations. The Commission and the Member States may take them into consideration when analysing the draft technical regulation in question and when preparing comments or detailed opinions to be sent to the notifying Member State with a view to the removal of protectionist elements identified in the draft.

If the options available to citizens and undertakings of the European Union under Directive (EU) 2015/1535 are to be exercised in full, private individuals and businesses must consult the sources of information made easily accessible by the Commission.

## **1. TRIS database**

Recital 7 of the Directive (EU) 2015/1535 reads: *“The aim of the internal market is to create an environment that is conducive to the competitiveness of undertakings. Increased provision of information is one way of helping undertakings to make more of the advantages inherent in this market. It is therefore necessary to enable economic operators to give their assessment of the impact of the national technical regulations proposed by other Member States .....”*

In order to facilitate citizens’ and industry’s access to national technical regulations, the Commission has developed a comprehensive database of all notified draft texts (and the final texts as adopted by the Member States) called TRIS (Technical Regulations Information System) which is accessible to the public on the Europa website.<sup>100</sup>

In addition to the well elaborated “Search” function, using various criteria such as notification number, country, date, product, key words etc., which allow to identify national draft technical regulations and also texts which were already adopted, any interested person can use the automatic “Alert System” via this TRIS website. All interested parties need to do is to register and select one or several notification categories. TRIS will automatically e-mail the subscriber when a new notified text in the chosen category or categories has been uploaded in the database.

## **2. Stakeholders contributions**

If citizens or industry considers that a draft under examination would subsequently cause problems for the internal market / is likely to hinder trade relations in the European Union, he/she is invited to make any concerns known and to communicate his/her comments either to the Commission or to the authorities responsible for the draft in the particular Member State via e-mail or postal letter.

Contributions, in which stakeholders inform the Commission about their position on a draft technical regulation, are highly appreciated and considered very useful, as they may contribute to a more comprehensive understanding of national draft legislation.

To guarantee the implementation of the principles enshrined in Recital 7 of the Directive, the Commission departments have developed an IT functionality alongside TRIS that allows stakeholders to submit their comments in any EU official language in relation to any given notification directly via the TRIS.

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<sup>99</sup> <http://ec.europa.eu/growth/tools-databases/tris/en/>

<sup>100</sup> <http://ec.europa.eu/growth/tools-databases/tris/en/>

The functionality “*Contributions*” in the ‘Technical Regulation Information System’ (TRIS) database, is available at:

<http://ec.europa.eu/growth/tools-databases/tris/en/>

This functionality allows submitting contributions on any notification for which the standstill period is still ongoing. Contributions can be submitted in the TRIS database in a publicly visible manner or as “confidential”. In the latter case, only the Commission services will be aware of the contribution.

As soon as the stakeholder has uploaded a contribution in the correct form and required format, the Commission service responsible for the management of the procedure acknowledges receipt of the contribution through a functionality in the TRIS database. The contribution is immediately transferred to the relevant Commission departments in charge of the specifically concerned EU legislation.

In order to be taken into account, contributions must be submitted as early as possible during the standstill period.

Nevertheless, the position of stakeholders cannot bind the Commission when deciding whether to react or not in relation to a given notification or when deciding the modality(ies) of its reaction or the grounds in which it is substantiated. Indeed, different stakeholders may submit different (and even contradictory) positions on a given notification. In that context, it is essential to underline that the Commission takes formal decisions independently, strictly according to EU law and the case-law of the ECJ, in the light of the information in its possession and in line with its internal decision-making rules.

Finally, the contributions made by interested parties are not replied by the Commission, given the strict timeline and the fact that it receives several hundred notifications of national draft technical regulations as well as thousands of related submissions from stakeholders per year.<sup>101</sup>

### **3. National contact points**

Interested parties may also react to the text of draft technical regulations by sending their contribution to the central units of the Member States (listed in TRIS website<sup>102</sup>) which are responsible for notifying the Commission of national draft technical regulations.

### **4. Access to documents**

The dialogue between the notifying Member State and the Commission / other Member States is not public. In the TRIS database, it is indicated whether the Commission or Member States sent comments or detailed opinion, but the content of those reactions cannot be consulted online.

However, since the judgment of the Court of Justice of the European Union of 7 September 2017<sup>103</sup>, the exchanges which take place under Directive (EU) 2015/1535 should be disclosed

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<sup>101</sup> Decision in case 2204/2018/TE on how the European Commission dealt with comments submitted under the notification procedure set up by the EU Single Market Transparency Directive.

<sup>102</sup> <https://ec.europa.eu/growth/tools-databases/tris/en/contact/member-states-list-of-central-units/>

<sup>103</sup> Case C-331/15 P *France v Schlyter* EU:C:2017:639.

upon request under Regulation (EC) 1049/2001<sup>104</sup>, even during the standstill period. The exceptions to this principle of transparency are:

- when one of the exceptions laid down in Regulation (EC) 1049/2001 applies, and
- when, in the circumstances of a particular case, access to the detailed opinion in question would specifically and actually undermine the objective of preventing a technical regulation that is incompatible with EU law being adopted.

Whenever the Commission receives a request of access to documents originating from a Member State, the Commission consults the Member State author of the document and the documents are disclosed only for information.

## **5. The inapplicability of the non-notified technical regulations**

The above cited sources of information enable private individuals and other interested parties to be informed of the notifications and to ensure that technical regulations with which they are obliged to comply have indeed been notified. If this is not so, they can assert their rights before the national judges through reference to the case law of the CJEU.

The *CIA Security* judgment and the *Unilever* judgment, delivered under the preliminary ruling procedure by the Court of Justice, are key elements in the protection of private individuals against failure on the part of Member States to fulfil their obligations under Directive (EU) 2015/1535.<sup>105</sup>

These judgments specify the consequences of the adoption of a technical regulation in breach of the obligations laid down by Directive (EU) 2015/1535: private individuals can invoke Articles 5 and 6 of the Directive before the national court, which must refuse to apply a national technical regulation that has not been notified in accordance with the Directive or which has been notified but has been adopted before the expiration of the standstill period laid down by the Directive.

Private individuals and enterprises have the possibility to ensure that any technical regulation adopted by a Member State is monitored before its adoption by the Commission and the other Member States (with the exceptions mentioned in the Directive). If this is not the case, a company, for example, can cite the inapplicability of the regulation in question, should it be accused of non-compliance by an authority. In the event of any national court proceedings resulting from the matter, the court must then set aside the application of the regulation and cannot, as a result, regard it as having been breached.

Since 1996, these judgments have been repeatedly upheld by the Court of Justice, consulted by national courts asking for a preliminary ruling.<sup>106</sup>

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<sup>104</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

<sup>105</sup> Judgment of 30 April 1996 in Case C-194/94 *CIA Security* EU:C:1996:172 and judgment of 26 September 2000 in Case C-443/98 *Unilever* EU:C:2000:496.

<sup>106</sup> Case C-226/97 *Lemmens* EU:C:1998:296, Case C-285/15 *Beca Engineering* EU:C:2016:295 and Case C-336/14 *Ince* EU:C:2016:72, Case C-95/14 *Unic and Uni.co.pel* EU:C:2015:492, Case *VG Media*, C-299/17, EU:C:2019:716, etc.

This sanctioning of the principle of the non-applicability to third parties of national technical regulations which have not been notified, supports the position which had been already adopted by the Commission in 1986<sup>107</sup> and enhances the protection of the interests of private individuals and enterprises in this respect.

As regards the extent of such a sanction, even though Article 5(1) of Directive (EU) 2015/1535 requires the entire draft of a law containing technical regulations to be communicated to the Commission, the non-applicability which results from the breach of that obligation extends, not to all of the provisions of such a law, but only to the technical regulations contained therein.<sup>108</sup>

It is important to underline that the Commission does not have the competence to declare a national act inapplicable for breach of the provisions of Directive (EU) 2015/1535. As mentioned above this is a prerogative of national courts.

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<sup>107</sup> Communication from the Commission concerning the non-respect of certain provisions of Directive 83/189/EEC, No 86/C 245/05, published in OJ C 245, 1.10.1986, p. 4.

<sup>108</sup> Case C-336/14 *Ince*, EU:C:2016:72, paragraph 68, and Case C-144/16, *Município de Palmela*, EU:C:2017:76, paragraphs 37 and 38.

## CONCLUSION

It is clear from a review of more than thirty years' experience with the implementation of the notification procedure during which time the Commission has screened around 20.000 draft national measures that significant progress has been made in preventing the emergence of new barriers to trade, simultaneously saving onerous legal, administrative and economic costs. In this respect the notification procedure may be considered a precursor for better regulation as it has proved to be an effective instrument of industrial policy and competitiveness which has created various channels of communication between all the main stakeholders. Consequently, it represents a model of regulatory transparency and administrative cooperation whose scope of application might be further extended and provide similar benefits in other sectors.

Although the completion of the Internal Market in 1993 does not appear to have diminished Member States' need to enact detailed legislation on products, they have become gradually familiar with the rules of the Internal Market, the principle of mutual recognition arising from the "*Cassis de Dijon*" precedent and the principles of transparency and co-operation, which now govern their activities in the field of technical regulations. Similarly, in the area of Information Society services, this mechanism has played an important educational role in the case of national authorities, notably as regards the need to make a clear legal distinction between operators acting under the freedom of establishment and those only wishing to provide cross-border services.

This is evident, among other things, from the inclusion of the mutual recognition clause in certain draft national legislative texts at the notification stage, from the goodwill shown by the Member States in correcting errors discovered by the Commission or by the other Member States in notified drafts and from the extended compliance of cases with the obligation to notify draft technical regulations.

In the majority of the cases where the Commission reacted in order to bring the national draft regulations into conformity with EU law, Member States agreed to carry out the necessary changes and to align their legislation, thus avoiding the launching of the more cumbersome infringement procedures by the Commission. The cooperation and discussion fostered between Member States through the notification procedure is evidenced, for instance, by the fact that between 2016 and 2018 Member States exchanged 160 detailed opinions.

This progress in European integration, which facilitates the maintenance and growth of trade, is the fruit of the joint efforts of the Commission and the Member States. By acting together to prevent the emergence of new technical barriers to trade, they reduce the need for legislation at EU level, and at the same time enhance the quality of the technical regulations adopted at national level. The Single Market Transparency Directive (Directive (EU) 2015/1535) is the key instrument of EU policy to combat barriers to trade, which has made this possible.

Despite its success, the procedure laid down by Directive (EU) 2015/1535 could still be improved. This requires clear identification of the points in need of improvement.

With regard to the procedure for the provision of information applicable to technical regulations and rules on Information Society services, experience has shown that in some cases Member States are failing to notify their drafts, in breach of the provisions of the Directive, or are applying some of these provisions erroneously as a result of insufficient knowledge of the procedure on the part of the bodies responsible for preparing the texts of these regulations. The Commission intends to pursue

its information activities in this area, in particular through enhanced dialogue with the national authorities.

This is already happening through yearly visits to Member States, where the Commission gets to present national authorities and economic operators with the opportunities and obligations in relation to the Single Market Transparency Directive.

Moreover, although the online TRIS database has provided a breakthrough in transparency and accountability, there is room for improvement. Concretely, the informatics system needs a technical overhaul to meet the demands and possibilities of today's digital tools.

Finally, the Commission appreciates stakeholders' increased participation in the examination of draft measures. Several European stakeholders exercise a high degree of "legislative vigilance" and are very active in defending their legitimate interests by informing the Commission or the national authorities about certain drafts which, if adopted, would create technical barriers. The involvement of individual enterprises and particularly small and medium-sized businesses, which are often more reserved, could be improved. They should not hesitate to seek information and speak up, even in a confidential way, when they consider that the technical regulations being prepared in Member States in which markets they participate could harm their interests, if adopted as they stand.

The Commission has taken some important steps to facilitate the participation of industry. In principle, notified drafts are translated into all official EU languages and are then available free of charge to the public on the Europa site, via the TRIS database. Furthermore, the Commission has set up an automatic alert system to which the public may subscribe. This permits economic operators to be automatically notified by TRIS via e-mail as soon as a notified draft is received in the selected product or Information Society service categories. The Commission has also installed a mechanism, which allows stakeholders to upload their positions on notified draft texts directly via TRIS in a publicly visible or confidential manner.

Final texts are also translated and uploaded to the online TRIS database. This will ensure further accountability and transparency, as all stakeholders will be able to check easily if their contribution had impact on the adopted version of the draft.

As seen, the work to improve the notification procedure and the TRIS database is an ongoing effort. In the spirit of the community culture that launched in 1983, we invite you – the community – to keep the Single Market Transparency Directive relevant and let us know of ways to improve the procedure. In the end, this is what will make a positive difference for Member States, EU citizens and economic operators in Europe.

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