

**Project: EuropeAid/132827/C/SER/RU**

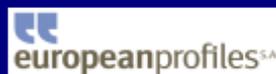
**“Approximation of EU and RF technical regulation and standardisation systems”**

## **Report # 2.4-1**

**Recommendations on approximating with EU regulations and policies, to recommend procedures and a policy for the use of standards in support of the technical regulations and the regular publication of standards lists**



**This project is funded by the European Union**



**in Consortium with**



This report has been prepared with the financial assistance of the European Commission and presented by European Profiles S.A. in consortium with Austrian standards Institute, SIQ Slovenian Institute for Quality and metrology, LGAI Technological Center S.A., EVOLUXER S.L. - The report does not reflect the views and opinions of the European Commission.

© All rights are the exclusive property of the European Commission.

# Content

- Introduction..... 4
- Procedures for the Development of the Lists of Standards in Support of Technical Regulations in the Eurasian Economic Union..... 5
  - 1. Legal base..... 5
  - 2. Procedure for Development of Lists of standards in support of CU TRs ..... 5
    - 2.1. Participants of the Procedure (article 2, the Regulations):..... 5
    - 2.2. Composition of the Lists ..... 6
    - 2.3. Stages of the procedure ..... 11
  - 3. Amendments to the existing Lists of standards (*articles 17-20, the Regulations*): ..... 15
    - 3.1. Amendment procedure ..... 15
    - 3.2. Safeguard clause..... 16
  - 4. Conclusions ..... 16
- Procedures for the Development of the Lists of Standards in Support of Technical Regulations in the European Union ..... 18
  - Revision of harmonised standards ..... 21

# Introduction

The European Union and the Eurasian Economic Union systems of technical regulation both include the concept of lists of standards, the compliance with which leads to a presumption of conformity with the essential requirements of the technical regulations. In other words, when a product complies with the applicable harmonised standards that are available, it is deemed to comply with the applicable technical regulations. This principle is one of the key elements of both systems.

Standards on the mentioned lists are called ‘harmonised standards’. Harmonised Standards create the linkage between technical regulation and standardisation, providing the technical details that can be used to show conformity with the broader requirements of regulations. Availability of harmonised standards is important for manufacturers because they provide a clear path to compliance with the often generally formulated requirements of technical regulations.

In discussions about standardisation with the business community in Russia, one of the most widely heard comments was that the lists of harmonised standards for the technical regulations in force have not been updated. Even for the technical regulation on low voltage equipment and the technical regulation on EMC, which apply to appliances that are subject to rapid technological developments, the lists have not been updated in the 3 years these technical regulations are in force.

**UPDATE: In December 2016, an updated to the list of standards for the technical regulation on low voltage equipment and the technical regulation on EMC was published.**

In this report, the adoption an amendment procedures for the lists of harmonised standards in the EAEU and the EU are compared, in order to determine if the procedures can be approximated and recommendations can be given to improve or speed up the process, and to ensure manufacturers can benefit from applying the latest standards.

# Procedures for the Development of the Lists of Standards in Support of Technical Regulations in the Eurasian Economic Union

## 1. Legal base

The legal basis for the adoption of lists of harmonised standards in the Eurasian Economic Union are provided by the following documents:

1) Agreement on unified principles and rules of technical regulation in the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation (signed on 18.10.2012) // *Соглашение о единых принципах и правилах технического регулирования в Республике Беларусь, Республике Казахстан и Российской Федерации (подписано 18.10.2012).*

2) Decision of the EEC Board of 25.12.2012 N306 “On approval of Regulations on procedure of development and approval of Lists of international and regional standards or, in the absents thereof, national (state) standards of the CU Member States, ensuring compliance with the CU TR and required for carrying out conformity assessment (confirmation of conformity)” (herewith – the Regulations) // *Решение Коллегии Евразийской Экономической Комиссии от 25.12.2012 N306 «Об утверждении Положения о порядке разработки и утверждения перечней международных и региональных стандартов, а в случае их отсутствия – национальных (государственных) стандартов государств-членов Таможенного союза, обеспечивающих соблюдение требований технического регламента Таможенного союза и необходимых для осуществления оценки (подтверждения) соответствия».*

3) Decision of the EEC Council of 20.06.2012 N 48 about Regulations on procedure of development, adoption, amending and repeal of CU technical regulations // *Решение Совета Евразийской Экономической Комиссии от 20.06.2012 N 48 о Положении о разработке, принятии, внесении изменений и отмены технического регламента Таможенного союза».*

## 2. Procedure for Development of Lists of standards in support of CU TRs

From the aforementioned documents the following rules and procedures for the development and adoption of the lists of standards in support of technical regulations can be deduced:

### 2.1. Participants of the Procedure (article 2, the Regulations):

The following persons and bodies are identified to play a role in the development and adoption procedure of the list of harmonised standards:

a) authorized technical regulation bodies of the Member States;

- b) authorized standardisation bodies of the Member States;
- c) authorized bodies of the Member States in the field of ensuring the unity of measurements;
- d) developer of draft technical regulation - a Member State body or a structural unit of the Commission may act as Developer, who is responsible for development of the technical regulation;
- e) other agencies involved into to the process of development of the draft technical regulation;
- f) the Eurasian Economic Commission;
- g) the Board of the Commission;
- h) stakeholders from Member States, including technical committees for standardisation and representatives of business community.

## **2.2. Composition of the Lists**

### **2.2.1. Principles**

The 'Agreement on unified principles and rules of technical regulation in the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation' sets up general principle of two Lists of supporting standards for each technical regulation:

- 1) List of standards, voluntary application of which results in a presumption of compliance with requirements of the technical regulations;
- 2) List of standards, providing rules and methods of testing (evaluation) and measuring, including rules for taking samples, required for application and compliance with provision of the technical regulation and conformity assessment of products (article 6).

The agreement states that the Regulations will set up particular principles of composition of the list of standards.

1. The Regulations sets criteria of priority for determination which standards should be included into list.

The following order of preference for including standards into List is given(*articles 4-6, the Regulations*):

- a) interstate standards developed on basis of international and (or) regional standards;
- b) national (state) standards of Member States, developed on basis of international and (or) regional standards;
- c) international and (or) regional standards (but not interstate standards) - (in the absence of international and (or) regional standards, developed on basis of international and (or) regional standards);

d) interstate and national (state) standards of Member States, developed not on the basis of international and (or) regional standards.

Exceptions from the order can be made if standards do not correspond with the objectives of the technical regulation, in particular because of climate or geographical factors and other reasons.

2. The draft Lists are developed in correspondence with **the Forms**, provided in *Annex 1 to the Regulations*.

These forms look like the following:

Form 1

This is the form for the List of standards, voluntary application of which results in compliance with requirements of the CU TR:

N п/п	Elements of the CU TR	Reference of standard	Title of standard	Notice
1	2	3	4	5
1				
2				
n...				

Form 2

This is the form for the list of standards, providing rules and methods of testing (evaluation) and measuring, including rules for taking samples, required for application and compliance with provision of the CU TR and carrying out conformity assessment of products:

N п/п	Elements of the CU TR	Reference of standard	Title of standard	Notice

1	2	3	4	5
1				
2				
n...				

Explanations on filling out the forms are given in Annotations below the forms. Both forms are provided with Annotations of the same content:

*“Annotations: 1. Column 2 contains constituent elements of TR (paragraph, sub-item, item, particle, annex) conformity to which can be confirmed through application of rules and methods of testing (evaluation) and measurements, including rules for taking samples, laid down in a standard.*

*2. Column 3 contains appropriate sections (items, sub-items) of a standard, if it is necessary to apply only specific sections (items, sub-items) of a standard, but not a standard in whole for carrying out conformity assessment of a product.*

*3. Column 5 contains information about the expiration date for application of a standard, in supersession of which a new standard has been developed (day – two Arabic numerals, month - two Arabic numerals, year – four Arabic numerals), and (or) information about transitional period, during which both replaced and replacing standard can be applied”.*

### **2.2.2. The Developer of Draft List**

According to articles 4 and 6 of the Decision of the EEC Council of 20.06.2012 N 48 *on Regulations on procedure of development of CU technical regulations*, the Developer of a technical regulation is a body designated by the Governmental organ (typically a Ministry) of a Member State responsible for development of the technical regulation. It is in the responsibilities of the Developer of the technical regulation to also develop the Lists of standards.

*Article 4: The Party (Government of a Member State), responsible for development of the technical regulation designates a body responsible for development of the technical regulation.*

Funding for development of the technical regulation is provided by the Party made responsible in the planning for the technical regulation. This Party typically is one of the Ministries of one of the Member States of the Eurasian Economic Union.

The Parties also designate the bodies to participate into the process of development of draft TR:

*Article 6: The Developer of the technical regulation is responsible for preparation of:*

- *The initial version of the draft technical regulation.*
- *The list of documents, including international, regional and national standards, other documents, adopted by international organizations (Rules, Directives, Guidelines) and valid technical regulations, requirements of which lay down the basis for drafting the draft technical regulation.*
- *Proposals on draft lists of standards supporting the technical regulation (**note: this is not the draft List of standards yet**).*
- *The draft of the EEC Board Decision which prescribes the procedure for enacting of the technical regulation and (or) contains transitional period provisions.*

Following the suggestions of authorized bodies, the Developer forms a working group for the development of the draft technical regulation composed of representatives of authorized standardisation bodies, representatives of relevant technical committees for standardisation and representatives of business community. However, the procedure for forming the working group is not described.

A document prepared by the Developer passes two preliminary stages, before it finally becomes a List of standards:

**Proposals on Lists of standards → Draft List of standards → Adopted List of standards**

The difference in legal status of Proposal and Draft is not clear from the text of the Decision. Probably, such division can be explained through the examination of process of the development of the technical regulation. It is stated in the legislation that the Developer starts to develop both the technical regulation and the List of standards simultaneously. As the Developer for the technical regulation and for the List are the same organisation, this is how it can be ensured that the List corresponds to the content of the technical regulation in development. Then when the draft List moves to the next stage, the standardisation bodies of the EAEU Member States provide their input on the lists.

The draft Lists of standards are made public after the technical regulation has passed public discussion stage of its development process. After public discussion and metrological expertise of the draft List the Developer, in cooperation with the standards bodies, prepares the final draft.

*Article 3, the Regulations: the Developer of the technical regulation simultaneously develops the initial version of the technical regulation and proposals on the Lists of standards in support of the technical regulations.*

*Article 3, the Regulations: After the draft technical regulation has been amended in accordance with results of public discussion and metrological expertise, the Developer*

*together with authorized standardisation bodies of Member States starts to develop the draft Lists of standards.*

*At the suggestion of authorities involved into development of the draft technical regulation and national standardisation bodies, the Developer may form a working group on development of the draft Lists composed of representatives of authorized standardisation bodies and stakeholders from Member States.*

In accordance with article 7 of the Regulations, the Developer:

- a) analyses requirements of the TR and draws up a list of objects of the technical regulation covered by its scope;
- b) analyses standards (keeping up with the order of preference) to determine if their provisions correspond to requirements of the technical regulation;
- c) determines the standards which have a scope covering the same objects under the technical regulation, voluntary application of which results in ensuring compliance with requirements of the technical regulation;
- d) determines standards which have a scope covering the same objects under the technical regulation, containing rules and methods of testing (evaluation) and measuring, including rules for taking samples, required for application and ensure of compliance with provision of the technical regulation and conformity assessment of products.

### **2.2.3. Conditions) for Including Standards into Draft List**

Standards can only be included in the List of standards if they fulfil the following conditions:

- 1) The standards on the list must be available;
- 2) they are binding between provisions of a supporting standard and objects of conformity assessment in the scope of technical regulation;
- 3) the appropriate methods of testing and measuring supporting a standard are available.

In more detail see below articles 8 and 9 of the Regulations:

*Conditions (requirements) for including standards into draft List of standards, voluntary application of which results in compliance with requirements of the technical regulation:*

- a) compliance with requirements of the technical regulation shall be provided through voluntary application of one or several standards, paragraphs, items or sub-items of a standard;*

*If standards, designated in article 4 of the Regulations are absent, by agreement of authorized standardisation bodies of Member States and authorities involved into development of the draft technical regulation, they choose a national standard of a Member State, which corresponds with objectives of the technical regulation;*

*b) compliance with the technical regulation requirements shall be ensured through availability of appropriate rules and methods of testing (evaluation) and measuring, including rules for taking samples*

*c) standards are included into the draft List on basis of the analysis of standards (see article 7 “b” of the Regulations), the scope of which extends to the objects of technical regulation under draft TR, and on basis of the analysis of those standards, which are referenced in the selected standards;*

*d) a specific standard, application of which assuring the compliance with the technical regulation, shall be supported by appropriate methods of testing (evaluation) and measuring.*

*Conditions (requirements) for including standards into the draft List of standards, providing rules and methods of testing (evaluation) and measuring, including rules for taking samples, required for application and compliance with provision of the technical regulation and conformity assessment of products to be observed by the Developer:*

*a) the draft List shall be made up of standards providing such rules and methods of testing (evaluation) and measuring and rules for taking samples, which are appropriate for ensuring implementation of the technical regulation, compliance and confirmation of conformity with its requirements;*

*b) standards, containing rules and methods of testing (evaluation) and measuring, shall be based on methodics of measurement, which are certified (validated) in accordance with legislation on ensuring unity of measurements of Member States;*

*c) methods of testing (evaluation) and measuring provided in standards, shall ensure appropriate accuracy and reliability of the measurement results.*

## **2.3. Stages of the procedure**

### **2.3.1. Composition**

See the paragraph 2.2. of this Report.

The Regulations doesn't provide the information about timeframe for the procedure of composition and the procedure of adoption on whole.

### **2.3.2. Public discussion**

After finishing of development of the draft Lists the Developer passes them to the Eurasian Economic Union Commission with explanatory note and notification of development in accordance with form, provide in Annex 2, attached (electronically and in hard copy) (*article 11, the Regulations*):

1	Party, responsible for development of drafts (Member State or the Commission)	
2	Developer of the drafts	
3	Grounds (reasons) for Development	
4	Mailing address, telephone number, fax number, e-mail for forwarding remarks (suggestions, comments) on the drafts	
5	Date of completion of public discussion  (final possible date of forwarding remarks (suggestions, comments) on the drafts)	

Date of drawing notification	
------------------------------	--

---

(Member of the Board (the Minister)                      (personal signature LS)                      (clarification of signature)  
on technical regulation)

According article 12, the Explanatory note to a draft List shall contain:

- a) brief characteristic of the standards, included into the draft List of standards;
- b) information about compliance of these standards with international and regional standards;
- c) rationale for including national (state) standards of Member States into the draft List of standards;
- d) information on requirements and objects within the scope of the technical regulation, for which standards, voluntary application of which results in compliance with requirements of the technical regulation, and standards, containing rules and methods of testing (evaluation) and measuring, including rules for taking samples, required for application and compliance with provision of the technical regulation and conformity assessment of products, are absent.
- e) proposals for the development of interstate standards;
- f) proposals for update of draft List of standards prepared on the basis of the results of monitoring of development of appropriate interstate standards by authorized standardisation bodies of the Member States, in accordance with the form, provided in *Annex N 3 of the Regulations*:

N п/п	Elements of the CU TR	Reference for standard	Title of standard	Reference, title of replacing standard	Commencement date for replacing standard	Notice
1	2	3	4	5	6	7
1						
2						
n...						

N п/п	Characteristic for measurement	Method of testing (evaluation) and measuring	Document regulating method with the date of its approval	Metrological characteristics of method (detection limit, sensitivity et al. as available)	Information about conduct of certification (validation) of methodics of test(evaluation) and measuring
1	2	3	4	5	6

h) proposals for update of measurement methods (tests) for assessing compliance with sanitary-epidemiologic and hygienic requirements of draft TR.

### **2.3.3. Publication & adoption**

The Commission of the Eurasian Economic Union is responsible for publication of draft Lists and explanatory note on their official web-site for the purpose of public discussion. The public discussion will take 30 calendar days. On the suggestion of the Commission or the governments of the Member States the period of public discussion may be extended (*article 12, the Regulations*).

Remarks (suggestions, comments) on the draft Lists of standards delivered by stakeholders from Member States and third countries are forwarded to the Commission, which provides their publication on the official website of the Commission on the Internet as soon as available.

Remarks (suggestions, comments) on the draft Lists of standards are passed from the Commission to the Developer as soon as available but not later than 10 working days after public discussion is closed (*article 14, the Regulations*). Within 15 working days after receipt of the Commission's remarks (suggestions, comments), the Developer together with the relevant standardisation bodies of the Member States finalizes draft lists of standards, as well as the explanatory note and submits them to the Commission with a statement containing information on finalizing the draft lists based on the results of the public discussion (*article 15, the Regulations*).

The Lists of standards are approved in accordance with the appropriate procedure by the Board of the Commission of the Eurasian Economic Union, and shall be published on the official website of the Commission on the Internet (*article 16, the Regulations*).

### **3. Amendments to the existing Lists of standards (*articles 17-20, the Regulations*):**

#### **3.1. Amendment procedure**

Amendment procedure for the adopted Lists of standards is the same as for development of draft Lists. Proposals on amendments are delivered by Member States or the Commission of the Eurasian Economic Unions (EAEU).

If the national (state) standards of that Member State are included in the Lists of standards, authorized standardisation body of a Member State shall provide the authorized standardisation bodies of other Member States with the official copies of the national (state) standards in the Russian language and in electronic format.

Simultaneously with the publication of the Lists of standards on the official website of the EAEU Commission, authorized standardisation bodies of the Member States are working on the development of interstate standards on the basis of national (state) standards of Member States, included in the list of standards.

Governments of Member States are responsible for preparation and submission to the EAEU Commission reasoned proposals for updating the Lists on the basis of the results of monitoring of adoption, application, update and withdrawal of the relevant standards at least 1 time per year from the date of entry into force of the technical regulation.

- a) In the event that the EAEU Commission is responsible for the development of a draft technical regulation, the Board of the Commission is responsible for preparation and approval of the updated version of the List on the basis of proposals for updating the List delivered by the Governments of the Member States.
- b) In the event that a Member State is responsible for the development of draft technical regulation, the EAEU Commission forwards to authorized standardisation body of the Member State the proposals for updating the List delivered by the Governments of the Member States. That body is responsible for preparation and approval of the updated version of the List of standards. The Authorized standardisation body forwards the updated version of the List to the EAEU Commission, which approves it, following the appropriate procedure.

If the standards included in the Lists of standards are replaced with the recently developed and adopted interstate standards the application of which requires a transition period, during which both the replaced and the replacing standards can be applied, the information about that is placed in the annexes to the updated version of the List of standards and shall correspond the form specified in Annex N 3 of the Regulations (see above – paragraph 2.3.3 of the Report).

Updated version of List of standards approved by the Board of the EAEU Commission shall be published on the Commission's official website.

## 3.2. Safeguard clause

Technical regulations currently have no provisions similar to Article 11 of the EU Regulation 1025/2012 (the so-called Safeguard Clause):

### *Article 11*

#### *Formal objections to harmonised standards*

*1. When a Member State or the European Parliament considers that a harmonised standard does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation, it shall inform the Commission thereof with a detailed explanation and the Commission shall, after consulting the committee set up by the corresponding Union harmonisation legislation, if it exists, or after other forms of consultation of sectoral experts, decide:*

*(a) to publish, not to publish or to publish with restriction the references to the harmonised standard concerned in the Official Journal of the European Union; EN L 316/22 Official Journal of the European Union 14.11.2012*

*(b) to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the Official Journal of the European Union.*

*2. The Commission shall publish information on its website on the harmonised standards that have been subject to the decision referred to in paragraph 1.*

*3. The Commission shall inform the European standardisation organisation concerned of the decision referred to in paragraph 1 and, if necessary, request the revision of the harmonised standards concerned.*

*4. The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 22(2).*

*5. The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 22(3).*

## 4. Conclusions

After studying the main rules and procedures as described in the main EAEU Commission's document on the topic (Decision of the EEC Board of 25.12.202 N306 on *Regulations on procedure of development and approval of Lists of international and regional standards or, in the absents thereof, national (state) standards of the CU Member States, ensuring compliance with the CU TR and required for carrying out conformity assessment (confirmation of conformity)*), the following can be noted:

1. The regulator's formulations are on the one hand quite general, for example when describing the principles, and on the other hand sometimes very specific, for example when it lays down the forms for execution of different work documents.

2. The prescription of the procedure of development and amendment of the Lists of standards itself is described rather brief and without explanation. This leads to questions, for example: As the Developer is certainly not a single person or body, but a chain of actors (Government-Developer (Gov.Agency)-standardisation bodies and other stakeholders), how are the interactions between the participants in the can be regulated? Also: how is the process of decision-making is going on during those stages of development, when several participants are involved?

3. Responsibilities of the Developer:

- a) analyse requirements of the technical regulation and draw up a list of ‘objects of technical regulation’ covered by scope of the technical regulation;
- b) analyse standards (keeping up with the order of preference) to determine if their provisions correspond to requirements of the technical regulation;
- c) determine the standards which have scope covering ‘objects of technical regulation’ under the technical regulation, voluntary application of which results in a presumption of with requirements of the technical regulation;
- d) determine the standards which have scope covering ‘objects of technical regulation’ under the technical regulation, containing rules and methods of testing (evaluation) and measuring, including rules for taking samples, required for application and ensure of compliance with provision of the technical regulation and conformity assessment of products.

What is unclear is how the quality of the work of the Developer is it checked, and against which criteria:

- If the Developer is not complying with that principles and conditions, can the EAEU Commission refuse to adopt the draft is no scenario for such a case? How can the Draft List of standards be amended? The Regulations prescribes the procedure only for amending of adopted List of standards and the amendment of the Draft List is not regulated within the procedure of development of technical regulation.
- Terms of the development procedure are not set.
- The technical regulations do not have a safeguard clause to initiate correction harmonized standards that still lead to non compliant or unsafe products.

# Procedures for the Development of the Lists of Standards in Support of Technical Regulations in the European Union

In the European Union, the rules for standardisation are regulated by the legal framework given in Regulation (EU) No 1025/2012. It defines a ‘standard’ as “*a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory*”. A ‘harmonised standard’ is simply defined as “*a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation*”. This means that the development of harmonised standards can only be done in case there is a technical regulation, or for technical regulations that are in the process of being drafted or adoption.

The overall procedure in the European Union leading to a harmonised standard giving a presumption of conformity is described below:

## **1. Planning of the Commission's standardisation request:**

The European Commission publishes its plans on future standardisation requests in an annual Union Work Programme for European standardisation in the way described in Article 8 of Regulation (EU) No 1025/2012. This Work Programme also identifies standardisation needs under future harmonisation legislation.

## **2. Preparation of a standardisation request:**

The European Commission prepares, according to Article 10(1) of Regulation (EU) No 1025/2012, a draft request consulting European standardisation organisations (CEN, Cenelec and/or ETSI), sectoral experts of the Member States and relevant stakeholders at European level according to Articles 10(2) and 12 of Regulation (EU) No 1025/2012.

## **3. Adoption and notification of a standardisation request:**

The European Commission adopts a request as a Commission implementing decision addressed to the ESO(s) after obtaining positive opinion from the Member States in accordance with the procedure laid down in Article 22(3) of Regulation (EU) No 1025/2012. The request is then notified to the relevant European standardisation organisations.

## **4. Acceptance of a standardisation request:**

Relevant European standardisation organisation indicates its acceptance on the request within the time limit given in Article 10(3) of Regulation (EU) No 1025/2012. National standardisation bodies are obliged to respect standstill requirements according to Article 3(6) of Regulation (EU) No 1025/2012,

which means that they will stop standardisation activities in areas where European standards are being developed. Relevant European standardisation organisation may apply for European Union financing (an action grant) on the basis of Chapter V of Regulation (EU) No 1025/2012. The European Commission informs the relevant European standardisation organisation within the timeline given in Article 10(4) of Regulation (EU) No 1025/2012 about the award of a grant.

#### **5. Programming and agreement of a work programme:**

Relevant European standardisation organisation(s) elaborates a (joint) work programme in line with the relevant request and presents it to the European Commission. When appropriate the European Commission may inform on priorities for the standardisation work.

#### **6. Drafting work:**

Responsible technical committee of a European standardisation organisation elaborates a draft European standard. European standardisation organisations follow the principles recognised by the World Trade Organisation (WTO) in the field of standardisation (coherence, transparency, openness, consensus, voluntary application and efficiency). In addition Regulation (EU) No 1025/2012 addresses directly applicable requirements on stakeholder participation and transparency of work programmes and draft standards in its Articles 3 to 5. The accepted request is one of the reference documents the responsible technical committee must follow during drafting work. According to Article 10(5) of Regulation (EU) No 1025/2012 relevant European standardisation organisation shall inform (reporting) the European Commission on activities undertaken and have a suitable means implemented together with the European Commission in lead to assess compliance of the drafted standards with the initial request.

#### **7. Public Enquiry:**

European standardisation organisations together with national standardisation bodies organise a public enquiry where all stakeholders may submit comments through national standardisation bodies. Article 4(3) of Regulation (EU) No 1025/2012 provides a procedure if a national standardisation body receives comments indicating a possible negative impact on the internal market.

#### **8. Integrating comments received:**

Responsible technical committee considers comments received during public enquiry and prepares the final draft European standard.

#### **9. Formal Vote:**

National standardisation bodies vote on the final draft in a formal vote where national standardisation bodies have weighted votes. The final draft is adopted if there is a simple majority of the votes cast in favour and if 71,00 % or more of the weighted votes cast (abstentions not counted) are in favour.

#### **10. Ratification and publication of a European standard (EN):**

Where the voting result is positive, the relevant European standardisation organisation ratifies and publishes the European standard (EN). As in this case the relevant EN supports Europe Union technical regulation and it was drafted on the basis of a European Commission request, this EN is a harmonised standard with the meaning of Article 2(1)(c) of Regulation (EU) No 1025/2012 — **however it does not yet provide a presumption of conformity.**

#### **11. Submission of references to the European Commission:**

Relevant European standardisation organisation transmits automatically references of a relevant harmonised standard to the European Commission. This information includes in particular the reference number and the title in all official languages of the EU.

#### **12. Verification of the conditions for publication in the Official Journal:**

According to Article 10(5) of Regulation (EU) No 1025/2012 the European Commission has to verify whether the relevant harmonised standard complies with the initial request. During this verification the European Commission checks in particular that the harmonised standard is covered by the relevant request and whether essential or other legal requirements ‘aimed to be covered’ are clearly indicated and covered by the standard. During this verification there is no need for a review of the technical content as the European Commission does not, in general, accept the technical content or takes responsibility for it. However already during this step the European Commission may also assess the adequacy of technical specifications given in a harmonised standard in satisfying corresponding essential requirements and this assessment may lead to non-publication of the references in the Official Journal.

#### **13. Publication of references in the Official Journal:**

According to Article 10(6) of Regulation (EU) No 1025/2012 the European Commission publishes the references of a harmonised standard in the Official Journal. This publication finally initiates a presumption of conformity with essential or other legal requirements covered by the relevant harmonised standard. A presumption of conformity is usually valid from the date the publication is done in the Official Journal and, in most common cases (see also point 4.1.2.5), can be removed by a formal objection or when a revised version of the harmonised standard is referenced in the Official Journal.

#### **14. National transposition:**

National standardisation bodies are obliged to transpose the relevant European standard as an identical national standard on the basis of the internal rules of the European standardisation organisations. According to Article 3(6) of Regulation (EU) No 1025/2012 they also are obliged to withdraw any national standards which are conflicting with a harmonised standard.

## **15. Formal objection:**

According to Article 11 of Regulation (EU) No 1025/2012 (172) a Member State or the European Parliament may dispute the publication of the references of a harmonised standard in the Official Journal. Through this process a Member State or the European Parliament may ask the European Commission to draft a Commission Decision in order to prevent or remove the presumption of conformity. A formal objection may be made as soon as the standard has been adopted and ratified (in case of CEN and Cenelec) or adopted (in case of ETSI) in accordance with the rules of the organisation concerned.

## **Revision of harmonised standards**

Harmonised standards translate the essential requirements into detailed technical specifications, methods of measurement to assess and/or declare the compliance with the essential requirements and, in some cases, numerical values to allow compliance with the essential requirements. Like any technical document, they are subject to change, or in other words to a revision.

The formal decision to revise a harmonised standard is, in principle, taken by the European standardisation organisations. This takes place on the basis of their own initiative, or following a standardisation request from the European Commission directly or, indirectly, based on a European Commission decision after a formal objection. The need for revision can result from the changes of the scope of the technical regulation (such as an extension of the scope to other products or a modification of the essential requirements), from the fact that the European Commission or a Member State of the EU challenges the contents of the harmonised standard, indicating that it could no longer give presumption of conformity with the essential requirements, or as a result of technological development.

When a harmonised standard is revised, the revision must be covered by a standardisation request to maintain the possibility of giving presumption of conformity. Unless the contrary can be deduced, the terms and conditions of the original request apply also for the revision of the harmonised standard. This does not exclude the possibility of a new request, in particular where the revision is related to shortcomings with respect to the essential requirements.

To give presumption of conformity, the revised standard must satisfy the general conditions according to the European Union technical regulation: the standard is based on a standardisation request, it is presented by the relevant European standardisation organisation to the European Commission and its reference is published by the Commission in the Official Journal.

Following its internal rules, the relevant European standardisation organisation lays down for the national standardisation bodies the latest date of withdrawal of the superseded edition of the national standard — in this case for the national standards which transpose the previous edition of the harmonised standard. The transitional period during which both the withdrawn harmonised standard and the revised harmonised standard may give presumption of conformity is set by the European Commission and published in the Official Journal. It is usually the time period between the date of publication of the reference of the new edition of the standard in the Official Journal and the date of withdrawal of the conflicting national standards — i.e. national standards which transpose the previous edition of the harmonised standards. It is the responsibility of the European Commission to

ensure that such transitional periods are of sufficient length and coherently set for all harmonised standards. After this transitional period, only the revised harmonised standard gives a presumption of conformity.

The European Commission may consider that, for safety or other reasons, the superseded version of the harmonised standard must cease to give a presumption of conformity before the date of withdrawal, set by the European standardisation organisation in question, or at a later date. In such cases, the European Commission fixes an earlier or later date after which the withdrawn harmonised standard will no longer give a presumption of conformity, and publishes this information in the Official Journal. If circumstances allow, the European Commission may consult the Member States prior to taking a decision to reduce or extend the period during which both versions of the standard give a presumption of conformity.

Unless decided otherwise on the basis of a proposal by the European Commission, the removal of the reference of a harmonised standard from the Official Journal after its revision does not automatically invalidate existing certificates issued by notified bodies; it only concerns the conformity that is conferred onto new conformity assessments that follow the new harmonised standard. Products produced according to the old certificate may still benefit from the continuing conformity with the essential requirements and may continue to be placed on the market until the end of the validity of the relevant certificates issued by notified bodies. However, manufacturers must assess the extent of the changes to the superseded version of the standard. The kind of action to be taken by the manufacturer depends on the nature of the changes in the harmonised standards, in particular whether these changes are material with regard to the coverage of the essential requirements and whether they concern the product in question. In addition, the notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The reference of the revised harmonised standard, together with the information concerning the superseded version of the harmonised standard, and the date when the presumption of conformity of the superseded version of the standard ceases are published together in the Official Journal. It is in the interest of the manufacturer to check every publication of the list of harmonised standards and to verify within it the validity of the harmonised standards he has applied in order to assess the conformity of his product. This is particularly essential in cases where the manufacturer declares conformity himself (in case of internal production control) and where the manufacturer wants to ensure continuous presumption of conformity for the products placed on the market.

In the context of guidelines agreed between the European Commission and European standardisation organisations there is an expectation that all revised harmonised standards should contain specific information indicating significant changes to a revised or amended harmonised standards and this information should be made publicly available (free of charge) by the standardisation organisations.

A harmonised standard may contain normative references to other standards. Through these references those other standards or parts thereof, become indispensable for the application of a given harmonised standard. Internal rules of the European standardisation organisations are applicable when making these normative references to other standards. Because of the nature of harmonised standards undated references to other standards, where relevant clauses aim to support essential or other legal requirements, should not be normally used. Undated references may cause situations where changes in specifications contained in harmonised standards and providing presumption of conformity are

uncontrolled and non-transparent — changes in normative references cannot be controlled within the meaning of Article 10(6) of the Regulation (EU) No 1025/2012 although by such changes a harmonised standard (a part of it) is de facto revised.

# Conclusions and Recommendations for Approximation of Procedures for the Development, Adoption and Amendment of the List of standards that support technical regulations

1. Both the European Union and the Eurasian Economic Union in their systems of technical regulation the concept of standards in support of their technical regulations, the compliance with which leads to a presumption of conformity with the requirements of the technical regulations these standards pertain to. However, the rules and procedures in both systems are completely different.

2. It has to be noted that an important difference between exists between the standardisation systems of the Eurasian Economic Union (EAEU) and the European Union. The European Union commissions European standards to the European Standards Organisations CEN, CENELEC and ETSI. In the Eurasian Economic Union, there are no regional standards bodies to which standards activities are commissioned. Instead, the EAEU refers to standards of the national standards bodies of the EAEU Member.

3. In the three year period after the transition period of the first three EAEU technical regulations have expired, no updated to the Lists of standards have been published. In comparison, the list of European harmonised standards for the Low Voltage Directive and EMC Directive both have been updated three times in the year 2016 alone. The lack of updates of the Lists of standards causes problems for the manufacturers that supply globally, or European wide, because they cannot use the latest versions of the standards that are accepted in other markets. This means they would have to develop different technologies for the EAEU market, and that the EAEU consumers and customers do not have access to the latest state of the art. Also it increased the cost of the products, due to repetition in testing and certification. Please note that due to the fast technological developments in electronics and electrical design, a period of three years is considered a long time. Many electronics are phased out after three years.

**UPDATE: In December 2016, an updated to the list of standards for the technical regulation on low voltage equipment and the technical regulation on EMC was published. However, the problem remains.**

4. Part of the problem may be cause by the fact that in the EAEU, there is no use of regional standardisation bodies, but instead the standards bodies of the Member States are consulted separately. This requires time, because all the national standards bodies need time to find whether they have standards for ‘objects of technical regulation’ of the technical regulations. They also need time to check whether the text of the standards and the technical regulations correspond.

The Commission of the EAEU does not have the competence nor a procedure to commission or mandate the development of harmonised standards for the Lists of standards, like its European Union counterpart has. Also, unlike the EU Commission, the EAEU Commission does not have procedures or mechanisms in place to check the quality of the content of standards and their correspondence with the content of the technical regulations. Such competence, procedures and mechanisms would greatly enhance the quality of the List of standards, as well as the speed with which amendments and new

standards may be introduced to the lists. It would also result in a further approximation of the EAEU and EU systems.

5. In practice, despite full compliance with harmonised standards, products may still cause incidents or otherwise in practical use be proven to be unsafe. If this is the case, the presumption of conformity of the standard should be withdrawn, and the standard (partially) repealed from the list of standards. In the European Union, this procedure is referred to as the ‘safeguard’-clause, and it is included in every technical regulation under the New Legislative Framework. In the Eurasian Economic Union regulations referred to in chapter 1, the safeguard clause is missing. Because of the importance that standards lead to safe products, and the unpredictability of product safety issues in the future, we highly recommend to include a similar safeguard clause like the EU regulations have in the EAEU technical regulations, and/or in the regulations that form the legal basis for the adoption and amendment of the Lists of standards that support technical regulations.