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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	20 December 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2017) 789 final
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

Delegations will find attached document COM(2017) 789 final.

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

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1. SUMMARY

Product safety is our common concern. When we buy a product, we want to be sure that it is safe and fulfils all legal requirements. Therefore, manufacturers often ask independent bodies, the so-called 'conformity assessment bodies, to verify if their products meet certain standards before they are sold. This is why we need reliable and competent conformity assessment bodies that do their work correctly. This is also the reason why the EU has put in place a system of accreditation of these conformity assessment bodies. National accreditation bodies check the competence and impartiality and independency of the conformity assessment bodies in their country.

This report gives an overview of how the accreditation provisions of Regulation (EC) No 765/2008 ('the Regulation') and CE marking were implemented between 2013 and 2017. The report on the implementation of rules on market surveillance and the control of products entering the EU market is included in the evaluation accompanying the enforcement proposal, which is also part of the "Goods Package".

This report confirms that the European accreditation infrastructure created by the Regulation has provided added value, not only for the single market but also for international trade. Accreditation has wide support from European industry and the conformity assessment community for ensuring that products meet the applicable requirements, removing barriers for conformity assessment bodies and helping entrepreneurial activities to flourish in Europe. The Regulation established a trustworthy and stable accreditation system in all Member States, as well as EFTA countries and Turkey. However, it faces the challenge of maintaining its solidity; i.e. keeping the whole accreditation system in line with the latest state of the art and ensuring that it is applied with the same stringency. This report also confirms that businesses are also better aware of the important role of CE marking on products in the single market.

This report was prepared in cooperation with the Member States through the accreditation sub-group of the 'Internal market for products' experts group.

2. ACCREDITATION

2.1. Policy considerations

The single market for industrial products is one of Europe's real success stories and its best asset in times of increasing globalisation. It is an engine for building a stronger and fairer EU economy. For over 80 % of industrial products, regulatory obstacles have been removed through the adoption of common European rules, creating a seamless market of over 500 million consumers. This has boosted competitiveness and innovation while at the same time Europe's consumers are offered an ever wider choice of safe products that comply with high standards for public interests such as safety, environment and health.

In order to address the priority set by the Juncker Commission relating to a deeper and fairer internal market[1], and as proposed in the Commission's Single Market Strategy[2], it is important to strengthen product compliance with the applicable

[1] https://ec.europa.eu/commission/priorities_en

[2] COM(2015) 550 final, *Upgrading the Single Market: more opportunities for people and business.*

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legislative requirements. Deepening the single market also means strengthening the conformity assessment system.

Conformity assessment bodies (laboratories, certification bodies, inspection bodies, environmental verification bodies etc.) are involved in assessing the conformity of products against the relevant legislative requirements, where the sectoral legislation calls for third party assessment, such as in the case of machinery, pressure vessels, medical devices, lifts, measuring instruments. Conformity assessment bodies are also used voluntarily by businesses to demonstrate compliance with standards or regulation even where it is not a legislation requirement. Accreditation ensures and confirms that these bodies have the technical capacity to perform their duties properly.

2.2 The impact of accreditation and functioning of the accreditation system

Accreditation is the confirmation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and where applicable any additional requirements, including those set out in relevant sectoral schemes.

The Regulation plays a key part in facilitating the free movement of goods in the internal market and international trade. Under its provisions, the Member States appoint a single National Accreditation Body that provides accreditation of conformity assessment bodies. The reliance on EU-wide harmonised standards is intended to create the necessary level of transparency and confidence in the competence of conformity assessment bodies, and to ensure that the European accreditation system is compatible with the international accreditation system.

While manufacturers remain responsible for their product's compliance with the applicable legislative requirements, a high technical capacity of conformity assessment bodies ensures that checks are precise and reliable. This contributes to the protection of public interests such as health and safety in the internal market.

The Regulation provides for a uniformly rigorous approach to accreditation in all Member States — so that ultimately one accreditation certificate is enough to demonstrate the technical capacity of a conformity assessment body throughout Europe. Therefore, the benefit of accreditation in the EU is that once a conformity assessment body has been successfully accredited according to the Regulation, Member States' authorities are obliged to recognise the accreditation certificate. This eliminates the unnecessary overhead of being accredited separately in every Member State and having the products checked by different conformity assessment bodies. This creates an environment favourable for developing businesses in the European market.

By the end of 2016, more than 34450 accreditations were delivered[3] (in regulated and non-harmonised areas) covering a wide range of activities and distributed as follows:

Type of accreditation	Number of accreditations for 2016
Calibration[4]	3245

[3] EA MLA report 2016, http://www.european-accreditation.org/information/ea-multilateral-agreement-report-2016-is-now-released .

[4] Calibration is mainly technical configuration of measuring devices.

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Type of accreditation	Number of accreditations for 2016
Testing[5]	18625
Medical examinations	3407
Product certification[6]	1752
Management systems certification	1355
Persons certification	480
Inspection[7]	5158
Proficiency testing providers (PTP)	176
Reference materials producers (RMP)	44
Verification 14065 (greenhouse gases)[8]	133
Eco-management and Audit Scheme (EMAS)	79
Total	**34454**

The process of restructuring and adapting to the Regulation is now completed[9]. All Member States as well as EFTA countries and Turkey have set up national accreditation bodies[10].

2.3. European accreditation infrastructure

As set out in the Regulation, the Commission recognised the European Cooperation for Accreditation (EA) as the European accreditation infrastructure[11]. It concluded an agreement in 2009 that specifies the detailed tasks of the EA and the principles of cooperation.

The EA has the fundamental function of determining the competence of the national accreditation bodies by means of peer evaluation[12]. Following the successful peer evaluation, national accreditation bodies became signatories to the EA Multilateral Agreement (MLA)[13] for the mutual recognition of accreditation certificates. A successful peer evaluation is the prerequisite for the mutual recognition of accreditation certificates. The peer evaluation system has demonstrated its strength by ensuring that national accreditation bodies have a high level of competence.

In addition, the EA has been working with interested stakeholders through its Advisory Board and participated in the international accreditation organisations the ILAC and the IAF[14].

The cooperation with the EA has been very fruitful on the whole. The importance of accreditation of conformity assessment bodies has substantially increased over recent years. Due to the work of the EA and its members it is recognised that accreditation

5 Testing is the determination of technical characteristics of a product without examining its conformity.

6 Certification is the demonstration over multiple checks that specific requirements (legislative or not) are fulfilled. Certification may encompass several inspections (see footnote 8 for 'inspection') and includes continuous monitoring.

7 Inspection is the examination of conformity with specific requirements (legislative or not) in a once-only check.

8 Requirements for bodies measuring/verifying emissions of greenhouse gases.

9 See Articles 4, 6 and 8 of the Regulation.

10 Their contact details are available on the Commission website at the following address: http://ec.europa.eu/growth/tools-databases/nando/

11 See Article 14 of the Regulation.

12 See Articles 10, 11 and 13 of the Regulation.

13 The EA Multilateral Agreement (EA MLA) is a signed agreement whereby the signatories recognise and accept the equivalence of the accreditation systems operated by the signing members, and also the reliability of the conformity assessment results provided by conformity assessment bodies accredited by the signing members.

14 International Laboratory Accreditation Cooperation / International Accreditation Forum.

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— as the last level of control in the European conformity assessment system — is essential for the correct functioning of a transparent and quality-oriented market and to safeguard a high level of protection of public interests such as health, safety and the environment.

2.4. Commission funding of European accreditation

In June 2014, the Commission and the EA signed the second framework partnership agreement for a four-year period (until June 2018). This framework partnership agreement allows financial support for the EA in fulfilling its tasks as laid down by the Regulation and meeting the objectives detailed in the guidelines. The EA activities eligible for EU funding include:

- carrying out technical work linked to the peer evaluation system;
- providing information of interested parties and participation in the international organisations in the field of accreditation;
- drawing up and updating of contributions to guidelines related to accreditation;
- giving assistance to third countries[15].

The framework partnership agreement stipulates that the EA and its secretariat could receive an annual operational grant for its ongoing work. At the time of writing this report, four annual operational grants amounting to EUR 600 000 and approximately 40 % of the overall EA budget have been disbursed.

Part of the grant has supported work related to the operation and management of the peer evaluation system which in 2013-2017 included[16]:

Year	Evaluations performed[17]	Total man-days of evaluation work
2013	11	673
2014	13	807
2015	10	583
2016	19	1138

The number of evaluators for 2016 by scope of activity is the following:

15 See Article 32 of the Regulation.

16 EA MLA report 2016, http://www.european-accreditation.org/information/ea-multilateral-agreement-report-2016-is-now-released.

17 Evaluations, initials, re-evaluations with or without scope extensions and extraordinary evaluations.

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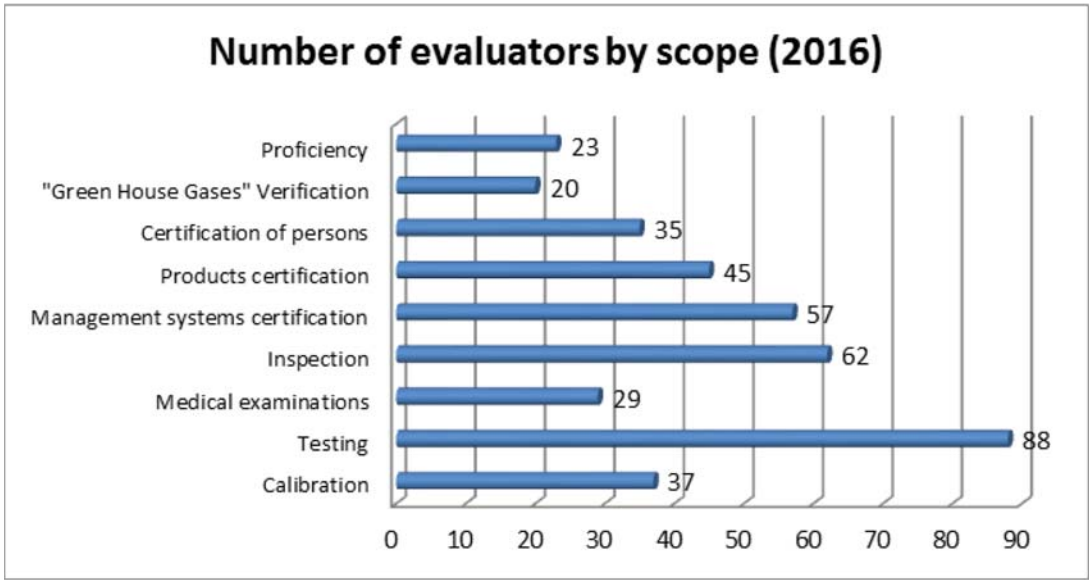

In 2016, the peer evaluation teams reported a total of 135 findings where corrective action was required by national accreditation bodies. The EA is monitoring how the corrective action is being implemented. In July 2014 one Accreditation Body has been suspended. Following the successful implementation of the corrective actions required by EA, the suspension has been lifted end 2014 following the results of an extraordinary evaluation by EA.

Regarding peer evaluation the EA's activities also include the continuous improvement of the peer evaluation system and the launch of peer evaluations for new conformity assessment activities.

The grant has also supported the EA's work on (i) harmonising accreditation criteria, (ii) developing, consolidating and implementing accreditation in the EU, and (iii) cooperating with accreditation organisations outside the EU, international organisations and private stakeholders.

Besides the annual operational grant, the framework partnership agreement with the EA also stipulates the possibility of action grants for specific projects. In this respect the EA participated in the following projects:

- In 2013 the EA signed a specific agreement with DG CLIMA on a grant for action regarding the implementation of accreditation in the context of Regulation (EU) No 600/2012[18]. The work related to this specific agreement was successfully concluded in February 2015.
- In 2012 the EA signed a service contract with EuropeAid for the 'Approximation of the EU and Russian Federation Accreditation Systems'. The work was successfully concluded in December 2015.
- In 2014 the EA signed a service contract with the JRC for 'Support services regarding the accreditation aspects of the project on a European voluntary Quality Assurance scheme for Breast Cancer Services underpinned by Accreditation and high-quality Guidelines'. The project is still ongoing at the time of writing this report.

[18] Regulation (EU) No 600/2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC.

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The Commission and the EA are currently discussing the third framework partnership agreement.

2.5. Accreditation in support of notification

Notification is the act of a Member State informing the Commission and the other Member States that it has designated a conformity assessment body under an EU harmonisation act, and that the body fulfils the relevant requirements set out in that act. Member States take the final responsibility for the competence of their notified bodies concerning the other Member States and the EU institutions.

Although accreditation is the favoured instrument for verifying the competence of conformity assessment bodies, other ways to evaluate the competence of conformity assessment bodies are allowed as well. In such cases, evidence must be given to the Commission and other Member States that the evaluated body complies with all the applicable regulatory requirements[19]. Furthermore, the notified body must undergo regular surveillance similar to the practice established by the accreditation organisations.

The proportion of notifications of accredited conformity assessment bodies increased by 34 percentage points between end 2009 and November 2017. At the end of 2009, before the entry into force of the Regulation, out of 2249 notifications 1089 concerned accredited conformity assessment bodies and 1118 concerned unaccredited bodies; i.e. 48.4 % of all notifications across all sectors were accredited. By November 2017, there were 2708 notifications of which 472 concerned unaccredited conformity assessment bodies while 2236 concerned accredited bodies; i.e. 82.6 % of all notifications were for accredited bodies.

Meanwhile, the EA developed the 'Accreditation for Notification' (AfN) package. It includes guidance documents and good practices and aims for more harmonisation throughout Europe when assessing notified bodies. The project was successfully concluded in 2016 and the EA and its members are implementing the results.

The following table shows the breakdown of notifications per Member State and piece of legislation[20].

19 Article 5(2) of Regulation (EC) No 765/2008.

20 State of play is 3 November 2017

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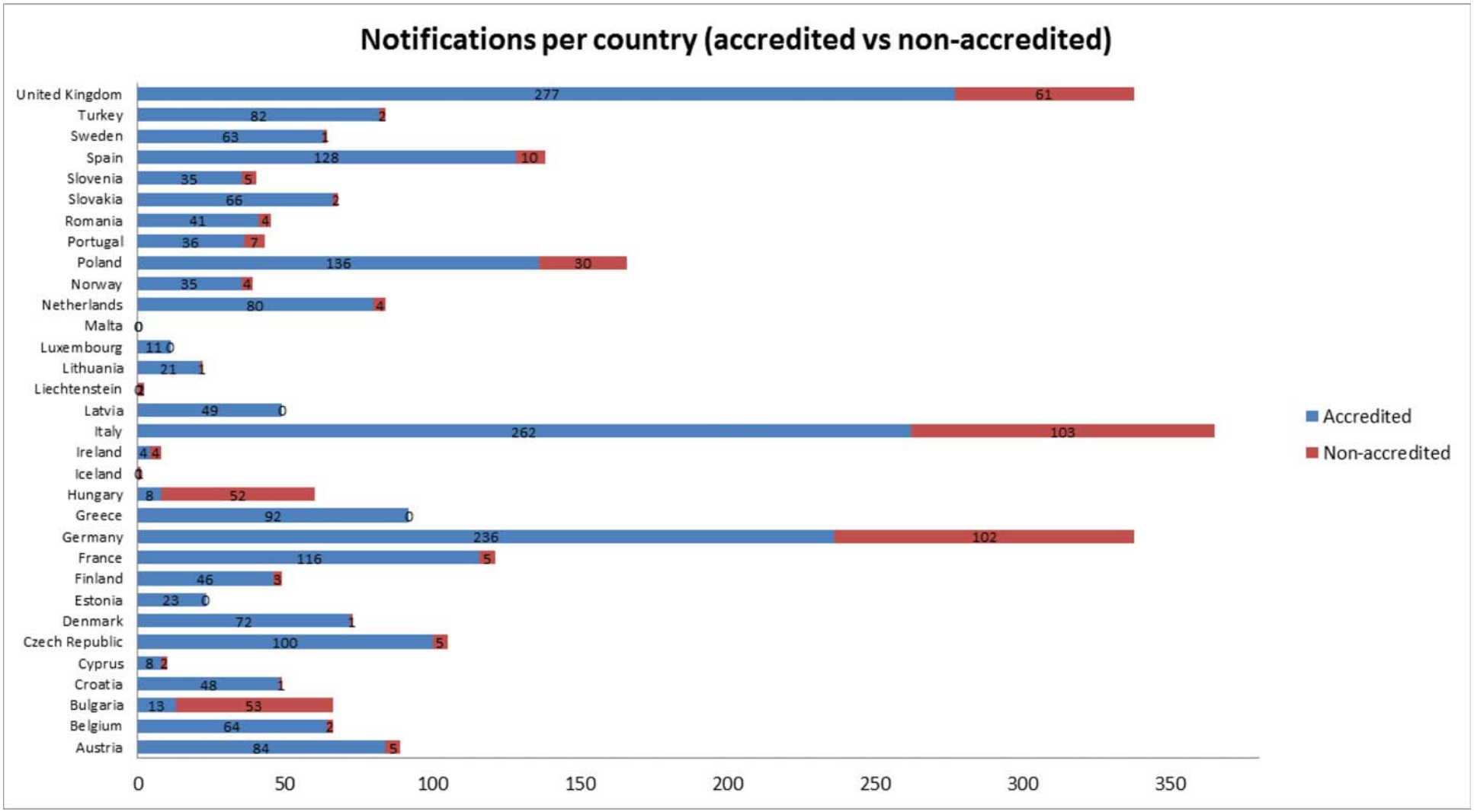

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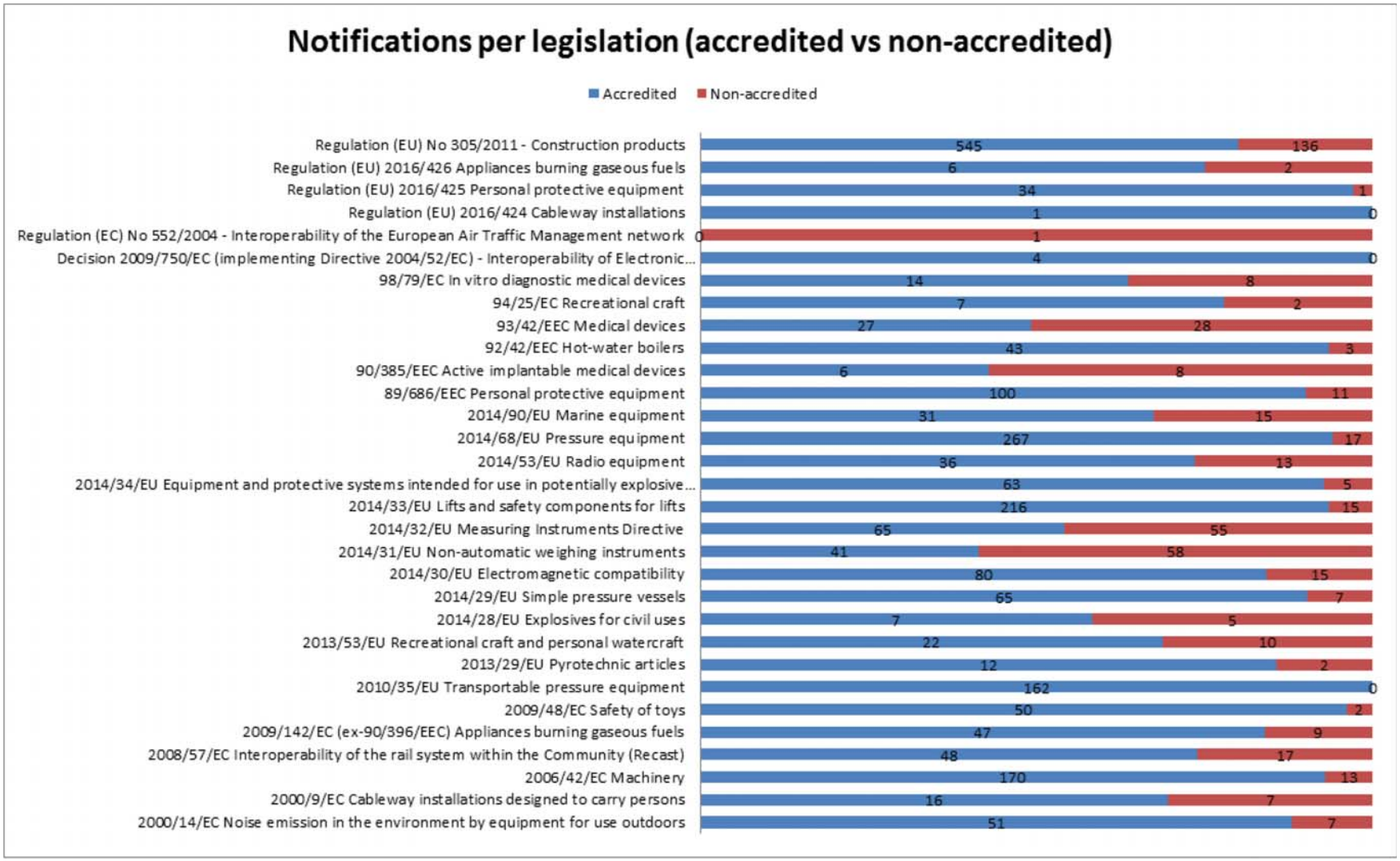

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2.6. International cooperation — Agreement with Canada

Upon the provisional entry into force of the EU-Canada Comprehensive Economic and Trade Agreement[21] on 21 September 2017[22], the CETA Protocol on the Mutual Acceptance of the Results of Conformity Assessment has replaced the previous Mutual Recognition Agreement with Canada of 1998. The Protocol expands its scope and substantially simplifies procedures for designating conformity assessment bodies to perform tasks for the purpose of meeting regulatory/legal requirements of both the EU and Canada.

Under the CETA Protocol, once designated, a conformity assessment body in the EU can test products for export to Canada according to Canadian rules and vice versa. This is particularly helpful to smaller companies as they don't pay twice for the same test, and the time to market is shortened as products are not tested and certified in the country of destination.

The Protocol relies on accreditation, which thus becomes an even more important pillar for international cooperation with third countries.

It is expected that EU and Canadian accreditation bodies will be eventually recognised as being able to perform accreditation that complies with the Canadian and EU regulatory/legal requirements respectively. For this purpose, the EA and the Canadian accreditation body, the Standards Council of Canada (SCC) concluded a cooperation agreement on 10 June 2016. Its purpose, among other things, is to exchange information and experts for on-site assessments to increase mutual confidence in the respective EU and Canadian accreditation processes.

Furthermore, following the CETA Protocol close cooperation between the EA and the SCC has been established to ensure consistency in assessing conformity assessment bodies against European and Canadian product legislations.

The sectors covered by the CETA protocol are:

- electrical and electronic equipment, including electrical installations and appliances, and related components;
- radio and telecommunications terminal equipment;
- toys;
- construction products;
- machinery, including parts, components — including safety components, interchangeable equipment, and assemblies of machines;
- measuring instruments;
- hot-water boilers, including related appliances;
- equipment, machines, apparatus, devices, control components, protection systems, safety devices, controlling devices and regulating devices, and related

21 *OJ L 11, 14.1.2017*.

22 Notice concerning the provisional application of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part, *OJ L 238, 16.9.2017*.

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instrumentation and prevention and detection systems for use in potentially explosive atmospheres (ATEX equipment);

- equipment for outdoor use as it relates to noise emission in the environment;
- recreational craft and their components.

2.7. Commission's measures for enforcing the accreditation provisions of the Regulation

The Regulation specifies that the Member States shall appoint a single National Accreditation Body. Yet, a few private entities claim that they are also performing accreditation. Therefore, the Commission opened infringement cases and requested that two Member States take measures to prevent 'non-national bodies' — self-styled 'accreditation bodies' that are not the officially appointed national accreditation bodies — operating in their territories from carrying out tasks that contradict the Regulation and to correct the description of their activities. The cases are still on-going.

Furthermore, as the Regulation allows operators to appeal/object against decisions of the national accreditation bodies and obliges each Member State to recognise the equivalence of accreditation certificates of other Member States' national accreditation bodies, the Commission questioned the relevant parts of a new accreditation law adopted by a Member State in 2015. Following the Commission's action, this Member State fully addressed the Commission's concerns by amending the law on accreditation to comply with the Regulation.

2.8. Legal developments related to accreditation in specific sectors

2.8.1 Data protection

Article 43(1) of the new General Data Protection Regulation[23] (GDPR) obliges Member States to offer both possible accreditation methods to certification bodies, i.e. by the national data protection supervisory authority established in accordance with data protection legislation and/or by the national accreditation body. These accreditation methods concern certification mechanisms falling within the scope of Article 42 of the GDPR.

By giving specific powers to independent supervisory authorities, the EU acknowledges the special features of personal data protection as a fundamental right enshrined in Article 8 of the Charter of Fundamental Rights and thus the need for special review and monitoring of the decisions of certification bodies.

The Commission encourages the sharing of experiences between the EA and the supervisory authorities of the GDPR. In this respect the EA's infrastructure and know-how will be an asset to ensure that all channels of accreditation under the GDPR are consistent.

[23] Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

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2.8.2 Food and feed

The new food and feed Regulation[24] introduces accreditation and states that 'the accreditation should be delivered by a national accreditation body operating in accordance with Regulation (EC) No 765/2008'. In this respect the Commission will monitor the EA's deployment of the accreditation infrastructure into the food and feed sector.

2.8.3 Cybersecurity

The Proposal for a Regulation on Cybersecurity[25] introduces accreditation and stipulates that 'the conformity assessment bodies shall be accredited by the national accreditation body named pursuant to Regulation (EC) No 765/2008 only when they meet the requirements set out in the Annex to this Regulation'. Furthermore, the Proposal lays downs that 'in duly justified cases' a European cybersecurity certificate can only be issued by a public (conformity assessment) body; the latter may be, among others, a national certification supervisory authority.

As a national certification supervisory authority must also supervise the compliance of the certificates issued by other conformity assessment bodies with the legislative requirements, the Commission in cooperation with the Member States will monitor the implementation of the Cybersecurity Regulation (once adopted), and ensure that the compliance of the certificates is supervised in an impartial and transparent manner.

2.9. Challenges

The Regulation has set a solid legal framework for accreditation. The main challenge now is to keep the whole accreditation system in line with the latest state of the art and ensure that it is applied with the same stringency.

Furthermore due to the wider use of accreditation, some national accreditation bodies may face more requests for accreditation in the future which may impact on their financial and human resources.

Another challenge is creating a better level playing field when accreditation is used for notification. A lot of work has already been done by EA with the "Accreditation for Notification" (AfN) package. The correct implementation of this project should be monitored. In this respect Member States in their role as notifying authorities have a major role to play.

Accreditation is increasingly being used in new policy areas. The wider use of accreditation and the general trust in accreditation is an important responsibility for the EA and the national accreditation bodies. Therefore, it is essential that the EA continues to receive EU support to help it implement its tasks. Furthermore it is important to maintain a high level of awareness and understanding of the accreditation system among its stakeholders in order to ensure its correct

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[24] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

[25] Proposal for a Regulation of the European Parliament and of the Council on ENISA (EU agency for Network and Information Security), the 'EU Cybersecurity Agency', and repealing Regulation (EU) 526/2013, and on Information and Communication Technology cybersecurity certification — ''Cybersecurity Act'', COM(2017) 477 final.

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implementation especially in the new policy areas. The Commission will continue to promote the use of accreditation in accordance with Regulation 765/2008 in any new proposals requiring conformity assessment.

3. CE MARKING

Regulation (EC) No 765/2008 lays down the general requirements and principles of the CE marking. Most new EU legislation on non-food products adopted since 2010 specifically requires products to carry the CE marking, and that the CE marking is subject to the general principles set out in Regulation (EC) No 765/2008.

In 2014 the Commission examined whether the current regime of CE marking is satisfactory. The results of the assessment show an overall satisfaction with the CE marking which is considered appropriate and effective. The assessment also showed that there is no need for any fundamental change in CE marking, although there is a need for greater consistency and to avoid having different requirements for different pieces of legislation and address the issue of products with multiple parts[26].

The Commission webpage dedicated to the CE marking serves as a one-stop shop for information on CE marking in all EU/EFTA languages[27] and is regularly updated. The number of visits to the CE marking web pages[28] demonstrates the importance of this information being made available to stakeholders.

At the same time, the number of written questions to the European Commission on CE marking has substantially decreased over the last four years (less than 100 questions per year compared to almost 400 four years ago).

The comprehensive information of the dedicated website increased the stakeholders' familiarity with the CE marking and their awareness of their rights and obligations stemming from EU harmonised legislation. Furthermore, the questions themselves are now more complex, detailed and refined, demonstrating good knowledge of the CE marking requirements.

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26 Commission staff working document SWD(2014)23 on the evaluation of the internal market legislation for industrial products, accompanying Communication COM(2014)25 on a vision for the internal market for industrial products.

27 https://ec.europa.eu/growth/single-market/ce-marking_en

28 616 489 visits in the period from 11 July 2016 until 27 September 2017.

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