EUROPEAN
COMMISSION

Brussels, 5.12.2022
COM(2022) 679 final

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 repealing Regulation (EEC) No 339/93

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 repealing Regulation (EEC) No 339/93

1. INTRODUCTION

This report provides an overview of how the provisions of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation ('the Regulation') were implemented between 2018 and 2022, as provided for under Article 40 of the Regulation.

This report does not constitute an evaluation of the up-to-date relevance and coherence of the framework for accreditation and CE marking. These aspects are evaluated under the "Evaluation of the New Legislative Framework (NLF)"[1], carried out by Commission in 2022.

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 The role of accreditation

Products placed on the market (such as construction products, toys or machinery) must be safe and comply with the applicable legislative requirements. While manufacturers must ensure that their products comply with the requirements, independent bodies, the so-called "conformity assessment bodies" or "certification bodies" verify if the products meet the applicable legislative requirements before they are sold. These bodies are also used voluntarily by businesses to demonstrate compliance with standards or market requirements even where it is not a legislative requirement.

Accreditation is the attestation by a National Accreditation Body that a conformity assessment body has the technical competence to perform a specific conformity assessment activity.

National Accreditation Bodies act as public authorities.

National Accreditation Bodies monitor and reassess the conformity assessment bodies they have accredited. Where a National Accreditation Body ascertains that a conformity assessment body is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, it takes appropriate measures to restrict, suspend or withdraw the accreditation.

[1] https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en

For products regulated at EU level and if the applicable legislation provides for the involvement of a conformity assessment body, nationally designated conformity assessment bodies — Notified Bodies — assess the product and issue an attestation of conformity before the product can be placed on the market.

Accreditation is the preferred means of demonstrating the technical competence of the Notified Bodies.

The Regulation establishes the legal framework for accreditation. The Regulation applies to accreditation used on a compulsory or voluntary basis[2].

Moreover, the Regulation recognises a body known as the European co-operation for accreditation (the EA) of which national accreditation bodies are members and which cooperates with the Commission.

By 2018, 35276 accreditations (initial accreditations and re-assessments) were delivered[3]. By the end of 2021 this number increased to 36765[4]. The number of "accreditations" is not the same as the number of accredited conformity assessment bodies. An "accreditation" refers to a specific conformity assessment activity (e.g. testing[5], certification[6]) . ***A conformity assessment body may be accredited in more than one conformity assessment activity and related sectors/scopes (e.g. toys, machinery) and thus may have more than one accreditation.***

2.2 The accreditation in the context of the EU policies

2.2.1 Single Market and Industrial Strategy

The New Industrial Strategy for Europe[7] and its 2021 update[8] stress the need for a deeper Single Market that empowers European companies of all sizes to innovate, scale-up and employ more people.

In this context, the "Long term action plan for better implementation and enforcement of single market rules"[9] puts the Single Market at the core of Europe's industrial transformation and provides for further facilitating the circulation of goods and services across the EU, while also protecting consumers.

A robust accreditation system that ensures reliable assessment of the product compliance and safety facilitates the free circulation of goods, deepens the single market and is thus a pillar of the implementation of the EU industrial policy.

---

2 See Article 3 of the Regulation.

3 EA MLA report 2018, https://european-accreditation.org/wp-content/uploads/2019/04/EA-MLA-report-2018_9-April.pdf

4 EA MLA report 2021, https://european-accreditation.org/wp-content/uploads/2022/04/EA-MLA-report-2021.pdf

5 Testing is the determination of technical characteristics of a product. Testing does not include the examination of the product conformity against (legislative or non-legislative) requirements.

6 Certification is the demonstration that specific requirements (legislative or non-legislative) are fulfilled.

7 COM(2020) 102 final, 10.03.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0102&from=EN

8 COM(2021) 350 final, 05.05.2021, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0350&from=EN

9 COM(2020) 94 final, 10.03.2020, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0094&from=EN

Furthermore, the Annual Single Market Report 2022[10] underlines the importance of development of certification schemes in core areas of the EU industrial and single market policies. In this respect, accreditation confirms that conformity assessment bodies providing certification have the technical capacity to perform their duties properly.

2.2.2 European Green Deal

Accreditation is an enabler for the successful implementation of the priorities set out in the European Green Deal[11] and the "Fit for 55 package delivering the EU's 2030 climate target on the way to climate neutrality[12]", wherever the ***assessment of product compliance against climate related and sustainability milestones*** is necessary.

2.2.3 Digital Transition

In the State of the Union Address in September 2021[13], President von der Leyen underlined the need for Europe to shape its digital transformation and secure digital sovereignty.

In this respect, the "2030 Digital Compass" laying down "the European way for the Digital Decade"[14] provides for the uptake of digital skills and the development of climate neutral and energy efficient digital infrastructures.

Accreditation ensures the competence of the entities in charge of performing assessments against the relevant requirements, i.e. related to energy and environmental efficiency.

2.2.4 Fight against Covid-19

The Commission Recommendation (EU) 2020/403 related to the Covid-19 threat[15] considered the conformity assessment as a crucial tool in the fight against the pandemic.

In this respect, accreditation ensured the reliability and the objectivity of the controls performed by conformity assessment bodies, ***even in times of influx into the market of a high number of new and unexperienced manufacturers*** as it is the case during the beginning of the Covid-19 pandemic.

2.2.5 Sectoral policies

Several pieces of EU sectoral legislation have recourse to accreditation in order to ensure a reliable assessment of the conformity of products and services against the applicable legislative requirements.

These pieces of legislation are covering a wide range of sectors such as: toys, machinery, construction products, pressure equipment, lifts, recreational craft, radio equipment, explosives for civil uses, equipment intended for use in potentially explosive atmospheres

---

[10] SWD(2022) 40 final, 22.02.2022 https://ec.europa.eu/docsroom/documents/48877

[11] COM(2019) 640 final, 11.12.2019, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0640&from=EN

[12] COM(2021) 550 final, 14.07.2021, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0550&from=EN

[13] https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_4701

[14] COM(2021) 118 final, 09.03.2021, https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52021DC0118

[15] Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat, C/2020/1712,OJ L 79I , 16.3.2020, p. 1–5, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020H0403

(ATEX), pyrotechnic articles, gas appliances, personal protective equipment including protective masks against Covid-19, medical devices, unmanned aircraft systems, vehicles, railways, fertilisers, food and feed, cybersecurity, carbon dioxide emissions from maritime transport, verification of greenhouse gas emission reports.

2.3 European Cooperation for Accreditation (EA) and Commission funding

As set out in the Regulation, the Commission recognised the European Cooperation for Accreditation (EA) as the centre of the European accreditation infrastructure and is providing funding to EA[16].

In December 2018, the Commission and the EA signed the third framework partnership agreement for a four-year period (until December 2022). This framework partnership agreement allows financial support for the EA in fulfilling its tasks. At the time of writing this report, four annual operational grants amounting to EUR 722 900 each have been disbursed under this framework partnership agreement. This sum corresponds approximately to 45.73 % of the overall EA budget for 2022.

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

The EA activities eligible for EU funding include the following :

- **carrying out technical work linked to the peer evaluation system;**
- **providing technical expertise to different Commission services for the inclusion of accreditation in legislative projects or in terms of implementing existing sectoral legislation;**
- **harmonising accreditation procedures;**
- **participation in the international organisations such as the ILAC and the IAF and international cooperation.**

In addition, the EA has been working with interested stakeholders through its Advisory Board.

Besides the annual operational grant, the framework partnership agreement with the EA also stipulates the possibility for the financing of specific projects. In this respect, the Joint Research Centre (JRC) awarded in 2020 to EA a contract of €410 000 for the continuation of the project "Support services regarding the accreditation/certification aspects of the project on a European voluntary Quality Assurance scheme for Breast Cancer Services". The project is still ongoing at the time of writing this report and is expected to be concluded in the first semester of 2023.

The cooperation with the EA has been very fruitful on the whole. EA is recognised as the natural "home" of the European accreditation system. Due to the work of the EA and its members, it is recognised that accreditation is essential for the enhancement of the competitiveness of the EU economy while protecting at the same time the public interest.

[16] See Article 14 of the Regulation.

2.4 The peer evaluation system

The peer evaluation system[17] of national accreditation bodies is the cornerstone of the European accreditation system. National accreditation bodies undergo peer evaluations of their systems, procedures and structures at the latest every four years.

The aim of the peer evaluation system is to ensure consistency and equivalence of accreditation practices across Europe so that the national public authorities and the wider market place, mutually recognise the services delivered by the accreditation bodies that have successfully passed the peer evaluation, and therefore accept the accreditation certificates and the attestations issued by the conformity assessment bodies accredited by them.

The EA has the fundamental function of organising the peer evaluation[18]. EA is organising, managing and operating the peer evaluation system.

Following the successful peer evaluation, national accreditation bodies became signatories to the EA Multilateral Agreement (MLA)[19] 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.

The operation and management of the peer evaluation system in 2017-2021 included[20]:

Year	Number of evaluations performed[21]	Total man-days of evaluation work
2017	18	1080
2018	18	1393
2019	16	935
2020[22]	7	335
2021	25	1764

For the period this report covers, the peer evaluation system reported the following numbers of findings where corrective action was required by national accreditation bodies. The findings are either proven "non-conformities" or "comments", i.e. suggestions for potential improvement. Until the year 2020 (included), the findings could also include "concerns" of the evaluators for possible non-conformities. These "concerns" are now covered under "non-conformities". National accreditation bodies are taking corrective action to remedy the "non-conformities" and address the "comments". The EA is monitoring how the corrective action is being implemented.

---

17 See Article 10 of the Regulation.

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

19 The EA Multilateral Agreement (EA MLA) is a 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.

20 EA MLA report 2020, https://european-accreditation.org/wp-content/uploads/2021/04/EA-MLA-report-2020.pdf and EA MLA report 2021, https://european-accreditation.org/wp-content/uploads/2022/04/EA-MLA-report-2021.pdf

21 Initial evaluations, re-evaluations with or without scope extensions and extraordinary evaluations.

22 Due to the pandemic, several peer evaluations have been postponed to 2021.

Year	Non-conformities	Concerns	Comments
2017[23]	116	185	131
2018[24]	84	139	81
2019[25]	71	170	125
2020[26]	62	94	56
2021[27]	239	No longer applicable	193

2.5 Accreditation in support of notification

Notification is the act of a Notifying Authority 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 have to ensure the competence of their Notified Bodies towards the other Member States and the EU institutions.

Accreditation is the most used instrument for verifying the competence of conformity assessment bodies wishing to be notified, for the following reasons.

- **The existence of the EA peer evaluation system ascertains the ability and competence of the National Accreditation Bodies and ensures consistency and equivalence of accreditation practices across the EU;**
- **Accreditation is based on Harmonised Standards and thus ensures EU-wide the same stringency of the evaluation of the conformity assessment bodies;**
- **Accreditation provides for established procedures for evaluation and regular surveillance of the accredited conformity assessment bodies;**
- **Accreditation provides for transparent appeal procedures against the decision of a National Accreditation Body.**

Nevertheless, besides accreditation, other procedures to evaluate the competence of conformity assessment bodies may be 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[28].

The proportion of notifications of accredited conformity assessment bodies increased over the years. This demonstrates the confidence of the economic operators to the merits of accreditation.

A Notified Body may subcontract part of its work. However, it can only subcontract tasks for which it has the competence itself. It may not be the case, that a Notified Body subcontracts a

[23] EA MLA report 2017, https://european-accreditation.org/wp-content/uploads/2018/10/ea-mla-report-2017.pdf
[24] EA MLA report 2018, https://european-accreditation.org/wp-content/uploads/2019/04/EA-MLA-report-2018_9-April.pdf
[25] EA MLA report 2019, https://european-accreditation.org/wp-content/uploads/2020/04/EA-MLA-report-2019.pdf
[26] EA MLA report 2020, https://european-accreditation.org/wp-content/uploads/2021/04/EA-MLA-report-2020.pdf
[27] EA MLA report 2021, https://european-accreditation.org/wp-content/uploads/2022/04/EA-MLA-report-2021.pdf
[28] Article 5(2) of Regulation (EC) No 765/2008.

part of the work, because it does not have the required competence and knowledge. Subcontracting does not entail the delegation of powers or obligations to the subcontractor.

In this respect, the National Accreditation Body and the Notifying Authority assess the extent to which the conformity assessment body intends to rely on subcontractors and they may withdraw and limit the scope of the accreditation and notification.

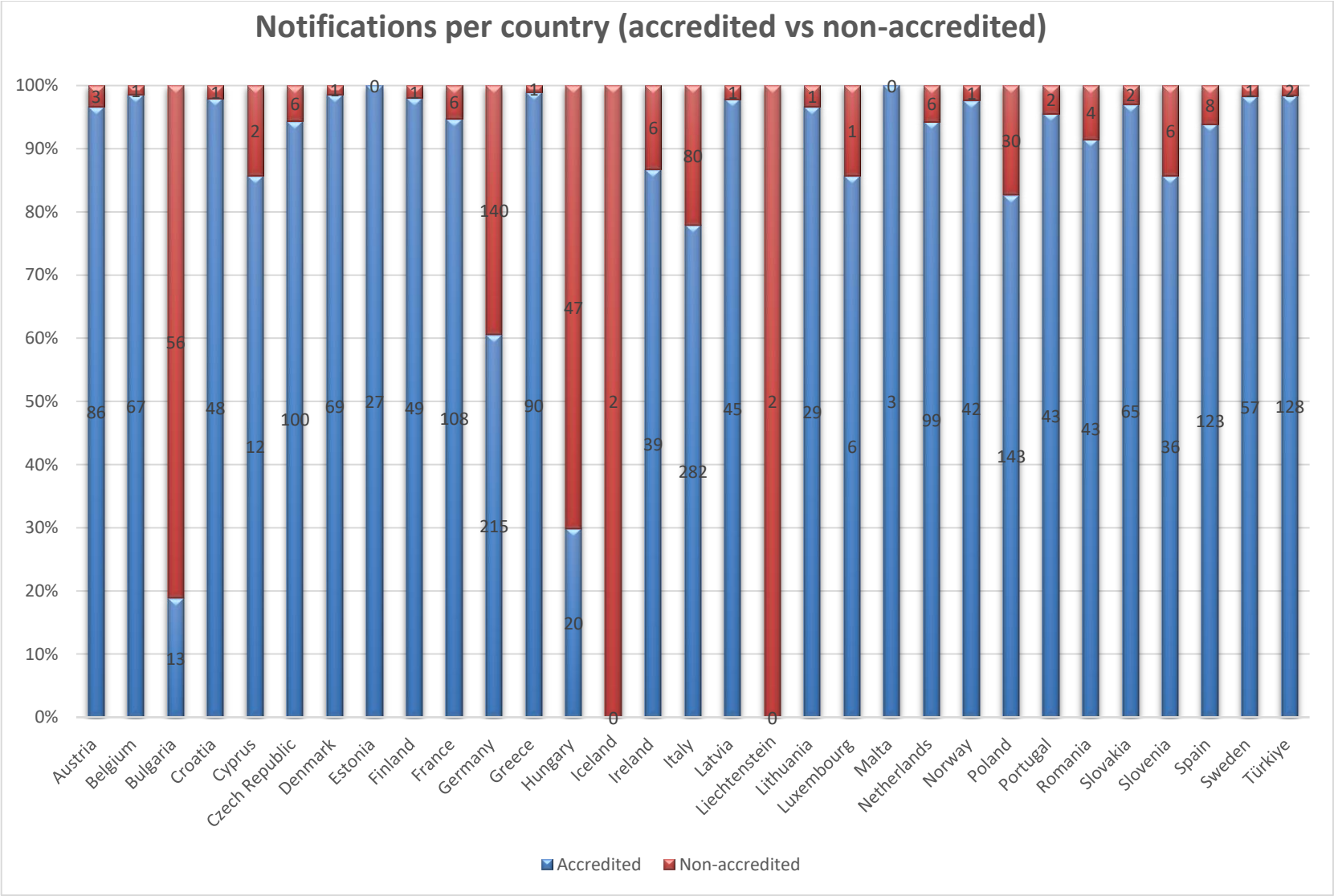
The following table summarises the evolution of the numbers of the accredited and non-accredited notifications[29].

Year	Total number of notifications	Unaccredited	Accredited	Accredited as % of all notifications
2009[30]	2249	1089	1118	48.4
2017[31]	2708	472	2236	82.6
2022[32]	2507	420	2087	83.2

The fact that the UK had a high number of Notified Bodies (accredited and non-accredited) explains the drop by 7.9 percentage points in the total number of notifications between 2017 and 2022. Nevertheless the percentage of the accredited notifications as percentage of all notifications between 2017 and 2022 increased.

The following tables show the breakdown of notifications per Member State and piece of legislation at the time of the writing of this report[33].

[29] As extracted from the information system for Notified Bodies (NANDO)
[30] Before the entry into force of the Regulation
[31] State of play is 3 November 2017
[32] State of play is 7 September 2022
[33] State of play is 7 September 2022


Notifications per country (accredited vs non-accredited)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Liechtenstein
Lithuania
Luxembourg
Malta
Netherlands
Norway
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
Türkiye
Accredited
Non-accredited

	Legislation	Accredited	Non-accredited
1	90/385/EEC Active implantable medical devices[34]	3	7
2	92/42/EEC Hot-water boilers	34	1
3	93/42/EEC Medical devices[35]	21	28
4	98/79/EC In vitro diagnostic medical devices[36]	10	9
5	2000/14/EC Noise emission in the environment by equipment for use outdoors	37	8
6	2006/42/EC Machinery	150	9
7	2009/48/EC Safety of toys	35	7
8	2010/35/EU Transportable pressure equipment	140	2
9	2013/29/EU Pyrotechnic articles	10	0
10	2013/53/EU Recreational craft and personal watercraft	21	11
11	2014/28/EU Explosives for civil uses	6	4
12	2014/29/EU Simple pressure vessels	62	8
13	2014/30/EU Electromagnetic compatibility	56	16
14	2014/31/EU Non-automatic weighing instruments	41	30
15	2014/32/EU Measuring Instruments Directive	58	31
16	2014/33/EU Lifts and safety components for lifts	220	13
17	2014/34/EU Equipment and protective systems intended for use in potentially explosive atmospheres (recast)	67	6
18	2014/53/EU Radio equipment	35	14
19	2014/68/EU Pressure equipment	283	32
20	2014/90/EU Marine equipment	29	17
21	2016/797 on the interoperability of the rail system	46	13
22	Regulation (EU) No 305/2011 Construction products	529	126
23	Regulation (EU) 2016/424 Cableway installations	14	4
24	Regulation (EU) 2016/425 Personal protective equipment	87	20
25	Regulation (EU) 2016/426 Appliances burning gaseous fuels	38	4
26	Regulation (EU) 2017/745 Medical devices	32	0
27	Regulation (EU) 2017/746 In vitro diagnostic medical devices	7	0
28	Regulation (EU) 2019/1009 Fertilising products	9	0
29	Regulation (EU) 2019/945 Unmanned aircraft systems and on third-country operators of unmanned aircraft systems	5	0
30	Regulation (EU) 2020/204 of 28 November 2019 on detailed obligations of European Electronic Toll Service providers	2	0

[34] As from 26 May 2021, the notified bodies designated under Directive 90/385/EEC are no longer able to issue new certificates under that Directive, but only allowed to carry out surveillance activities for certificates validly issued under that Directive in the transitional period, as established in Article 120 Regulation (EU) 2017/745 on medical devices (line 26 of the table).

[35] As from 26 May 2021, the notified bodies designated under Directive 93/42/EEC are no longer able to issue new certificates under that Directive, but only allowed to carry out surveillance activities for certificates validly issued under that Directive in the transitional period, as established in Article 120 of Regulation (EU) 2017/745 on medical devices (line 26 of the table).

[36] As from 26 May 2022, the notified bodies designated under Directive 98/79/EC are no longer able to issue new certificates under that Directive, but only allowed to carry out surveillance activities for certificates validly issued under that Directive in the transitional period, as established in Article 110 Regulation (EU) 2017/746 on in vitro diagnostic medical devices (line 27 of the table).

2.6 Implementation of the agreement with Canada

The EU-Canada Comprehensive Economic and Trade Agreement (CETA) contains a Protocol on the mutual acceptance of the results of conformity assessment ("the Protocol")[37]. The Protocol relies on accreditation.

Under the Protocol, once designated, a conformity assessment body in the EU can test products for export to Canada according to Canadian rules and vice versa.

EA and Canada's national accreditation body, the Standards Council of Canada (SCC) signed in 2019 a cooperation agreement providing for exchange of information as well as of experts for on-site assessments and for establishing procedures for the implementation of the Protocol[38].

The sectors covered by the Protocol are: Electrical and electronic equipment, Radio Equipment, Electromagnetic compatibility, Toys, Construction products, Machinery, Measuring Instruments, Hot-water boilers, Equipment and protective systems intended for use in potentially explosive atmospheres, Noise emission in the environment by equipment for use outdoors, Recreational craft.

During the CETA Joint Committee of 25 March 2021, Canada and the EU took stock of the positive outcomes regarding the ongoing implementation of the CETA Protocol.

A guidance document was adopted by the Commission and published in the Official Journal of the EU on 1 September 2021[39]. The document addresses the following elements:

- The scope of the Protocol;
- The conditions for the recognition (and the cessation of the recognition) of the accreditation and conformity assessment bodies established in the other's territory;
- The acceptance of reports of recognised conformity assessment bodies;
- The ways market surveillance or enforcement authorities shall verify conformity of the products assessed by a recognised conformity assessment body established in the other's territory.

During the CETA Joint Committee of 8 March 2022, Canada and the EU acknowledged the positive developments in the implementation of the CETA Protocol and agreed to work towards extending the scope of mutual acceptance of results of conformity assessment to additional sectors.

2.7 Remote assessment techniques

Since the outbreak of the Covid-19 pandemic, remote methods are used more and more in the accreditation and conformity assessment processes.

---

[37] OJ L 11, 14.1.2017, p. 567

[38] https://european-accreditation.org/implementation-of-ceta-ea-renewed-with-scc-the-bilateral-cooperation-agreement/

[39] Commission Notice - Implementation Guide for the Protocol to the CETA Agreement between Canada, the European Union and its Member States regarding the mutual acceptance of the results of conformity assessment, OJ C 351, 1.9.2021, p. 1

A main task is thus the systematic integration of remote assessment methods into the accreditation and conformity assessment processes while ensuring that the assessments maintain their reliability and stringency.

In this respect the following elements have to be taken into account:

- As ***accreditation is based on Harmonised Standards***, and many of them do not provide explicitly for remote assessment techniques, it is imperative to ensure that their application in the context of these techniques does not put at risk the health and safety of products in the EU and the role that Notified Bodies play in conformity assessment.

- The degree of use of remote assessments may depend on ***the specificities of the sector concerned*** such as the complexity of the product and the technology in question, the impact on the public interest, the size of the operator concerned and the nature of the production process (e.g. mass production or small series production).

Currently, accreditation and conformity assessment stakeholders are still gathering experience from the use of the remote assessment techniques and are debating about the following elements:

- The potential of the remote assessment techniques to ***complement on-site assessments***;
- Their ***benefits*** e.g. in terms of efficiency, cost reduction and pandemic-proofness;
- Their ***effectiveness and reliability*** in comparison to the on-site evaluations;
- Whether they can be used also during the initial evaluation of a conformity assessment body or ***only for the monitoring*** of accredited bodies;
- Whether there are parts of the accreditation and conformity assessment that ***by default cannot be carried out remotely*** or even whether there are whole product sectors where evaluations have to be always on-site;
- The ***need to modify the existing accreditation and conformity assessment processes*** in order to facilitate the use of remote assessment techniques without endangering the reliability and the objectivity of the processes.

The experience gathered to date and the questions remaining open do not allow at the time of writing this report to predict the exact way the remote assessment techniques will be used in the future. It is expected that regulators and stakeholders will crystallise their opinions in the foreseeable future. In the meantime stakeholders consider the on-site methods as the regular ones.

3. CE MARKING

3.1 The role of CE marking

Once the product conformity against the applicable EU legislative requirements is demonstrated, the manufacturer affixes, on its sole responsibility, the CE marking on the product.

By affixing the CE marking the manufacturer indicates, under its sole legal responsibility, that the product is in conformity with the applicable requirements set out in the EU legislation providing for its affixing.

CE marking is thus a key indicator of a product's compliance with EU legislation and the visible part of an assessment procedure laid down in EU legislation applying to the product in question. The applicable EU legislation lays down if such a product assessment is performed, either only by the manufacturer itself or under the involvement of a notified conformity assessment body.

The manufacturer, whether established inside or outside the Union, is the entity ultimately legally responsible for the conformity of the product with the provisions of the Union harmonisation legislation and for the affixing of the CE marking; independent of the fact whether a notified conformity assessment body was involved in the product checks or not.

The Regulation establishes the legal framework for the CE marking.

Several pieces of EU sectoral legislation provide for the affixing of the CE marking. These pieces of legislation are covering a wide range of products such as: toys, machinery, pressure equipment, construction products, lifts, recreational craft, radio equipment, explosives for civil uses, equipment intended for use in potentially explosive atmospheres (ATEX), pyrotechnic articles, gas appliances, personal protective equipment, medical devices.

3.2 Exchange with the stakeholders

Replying to the questions from stakeholders on the CE Marking, the Commission stressed the following elements:

- ***The CE marking is not a marking of origin and does not indicate that the product has been manufactured in the European Union.*** Economic operators, whether established inside or outside the Union, must affix the marking when their products are intended for the EU market and therefore they must comply with the EU legislation.

  The CE marking is also not a sign that the products have been approved by a national or other authority.

- Not all products are CE-marked. ***Only if the applicable legislation provides for it, then the product in question has to be CE-marked.***

  Thus, the CE marking does not refer to the manufacturer but to the product. This means that one company can produce a number of items, some of which will be CE-marked while the others will not.

- ***There is neither authority "granting" the CE marking nor any CE marking "representative";*** the CE marking is a declaration of the manufacturer. Nevertheless, the EU legislation provides for a set of documents that need to accompany every product that is CE-marked: technical documentation and declaration of conformity.

- Where the involvement of a conformity assessment body in the conformity assessment procedure is mandatory in the relevant EU legislation, ***only notified conformity assessment bodies are allowed to be involved.***

- ***The CE marking provides the first indication*** that the necessary assessment can be assumed to have been carried out, before the product in question is placed on the market, in order to ensure its compliance with the legislative requirements.

  Nevertheless, ***market surveillance authorities control products made available on the market.*** Their aim is to ensure that products fulfil the applicable requirements providing a high level of protection of public interests such as health and safety, security, protection of consumers and protection of the environment.

3.3 Enforcement

National authorities detected the following number of cases of non-compliances related to the CE marking and/or its accompanying documentation[40].

Year	Number of inspections	Number of non-compliances
2017	9262	1347
2018	11648	1362
2019	13653	1257
2020	13181	2285
2021	15584	1716
2022[41]	12817	1974

4. CONCLUSIONS

The Regulation has set a solid legal framework for accreditation and CE marking. In this respect, the "Evaluation of the New Legislative Framework (NLF)", carried out by Commission services in 2022, acknowledges in line with this report the following:

- The adoption and practical implementation of ***the EU legal framework for accreditation is a very important achievement*** under the objective of strengthening the conformity assessment system in Europe;
- ***The provisions on CE marking are clear***, enhance its clarity and credibility, increase industry attention on CE marking requirements, strengthen the visibility of CE marking, and iron out minor inconsistencies between different pieces of legislation.

As accreditation and CE marking underpin the implementation of several EU policies, a main challenge is to reinforce their solidity and reliability. In this respect, the "Evaluation of the New Legislative Framework (NLF)" concluded in line with this report that it is important to:

- Ensure that the relevant Harmonised Standards are adopted through ***a quick and effective standardisation process*** and continue to be in line with the International Standards and to reflect the latest state of the art;
- Explore ways in ***which remote assessment methods can facilitate the accreditation and conformity assessment*** processes, where appropriate;

[40] As registered by the market surveillance authorities into the Information and Communication System for Market Surveillance (ICSMS), the EU wide cooperation mechanism for the national market surveillance authorities

[41] State of play is 22 September 2022

- Ensure that the National Accreditation Bodies and the Notifying Authorities have ***the resources to monitor*** the tasks the accredited Notified Bodies subcontract, especially when these tasks are performed in another Member State or a third country;
- Explore the ***potential of digitalisation*** for simplification of administrative obligations related to affixing of the CE marking.

Moreover, it is essential that the EA continues to receive EU support to help it implement its tasks and to ensure the coordination of accreditation activities as well as the operation of the peer evaluation system.

The Commission will continue to promote the use of accreditation and CE marking in any new proposals requiring conformity assessment.