



**Publication
Reference**

EA-INF/05: 2020

**Directory of
European legislations
and EU schemes with
provisions
to accreditation and/or
conformity assessment**

PURPOSE

This publication has been established to support National Accreditation Bodies by providing a comprehensive directory of EU legislations and schemes with relation to accreditation and conformity assessment according Regulation (EC) No 765/2008.

Authorship

This document has been prepared by the EA Secretariat.

Official language

The publication may be translated into other languages as required. The English language version remains the definitive version.

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Category: Information Document

Date of Publication: 20 April 2020

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INTRODUCTION

The aim of Regulation (EC) No 765/2008 is to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interest such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Community harmonisation legislation or any other relevant Community rules.

In order to reach these objectives, it was necessary to establish an overall framework of rules and principles in relation to accreditation, conformity assessment and market surveillance.

Regulation (EC) No 765/2008 provides a comprehensive framework for accreditation and to lay down at Community level the principles for its operation and organization.

The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements providing a high level of protection of public interest.

Moreover, transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered by the national public authorities as the preferred means of demonstrating the technical competence of conformity assessment bodies (CABs).

Due to the new accreditation system set out in Regulation (EC) No 765/2008, the number of European legislations with reference to accreditation and conformity assessment has been increased significantly.

Accreditation is not only the preferred means to demonstrate the competence of CABs in regard to the EU Product legislations, it is used also in many other regulated sectors such as environment, climate, food and feed, transport, data protection and cybersecurity.

All EU legislations are published in the Official Journal of the EU (OJEU), but there is no specific list of legislations which make use of accreditation and/or conformity assessment. Only the New Approach Notified and Designated Organisations (NANDO) Information System includes a list of product legislations (Union Harmonisation Legislations) relevant for so-called notified bodies (see <https://ec.europa.eu/growth/tools-databases/nando/>). In NANDO and on the EU Commissions' website you can find also the legislations and other relevant documents for the assessment of notified bodies.

In order to support the NABs, this document with the comprehensive directory of EU legislations and schemes with relation to accreditation and conformity assessment according Regulation (EC) No 765/2008 has been established.

We do not claim that this directory includes all EU legislations and schemes. In case that an EU legislation, which includes provisions to accreditation and conformity assessment according Regulation (EC) No 765/2008, is missing, please inform the Secretariat.

The directory provides the information, whether accreditation is defined in the specific legislation as mandatory or voluntary (if applicable). But even if accreditation is not defined by the European regulator as mandatory, the national regulator can make the use of accreditation mandatory.

Note: The legislations can be found by search on EUR-Lex.

1 GENERAL LEGISLATIONS

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Regulation (EC) No 765/2008	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	Enterprise and Industry	Link to Regulation Link to summary			Accreditation Regulation
2	Regulation (EU) 2019/1020	Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011	Enterprise and Industry	Link to Regulation Link to summary			Amending Regulation (EC) No 765/2008 see Article 39 in EU 2019/1020

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
3	Decision 768/2008/EC	Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC	Enterprise and Industry	Link to Document Link to summary			Refer to Regulation 765/2008 for accreditation. Set out common principles and procedures which EU legislation must follow when harmonising conditions for marketing products in the EU and the European Economic Area. It lays down rules for CE marking.
4	Regulation (EC) No 764/2008	Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC	Enterprise and Industry	Link to Document Link to summary			Mutual recognition of the level of competence of accredited CAB's, ref. Art. 5. Repealed by Regulation (EU) 2019/515 (see below 1.25)!

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
5	Regulation (EU) 2019/515	Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008	Internal Market, Industry, Entrepreneurship and SMEs	Link to Document			Test reports or certificates shall be accepted, were issued by a CAB accredited for the appropriate field of conformity assessment activity in accordance with Regulation (EC) No 765/2008, ref. Article 5, 8.
6	Directive 2014/24/EU	Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC	Internal Market and Services	Link to Document			Where contracting authorities require the submission of certificates drawn up by a specific conformity assessment body, certificates from equivalent other conformity assessment bodies shall also be accepted by the contracting authorities. A conformity assessment body shall be a body that performs conformity assessment activities including calibration, testing, certification and inspection accredited in accordance with 765/2008, ref. Article 44.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
7	Directive (EU) 2019/882	Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services	Employment, Social Affairs and Inclusion	Link to Document Link to summary			The Directive must become law in the EU countries by 28 June 2022. EU countries must apply the measures from 28 June 2025. Reference to accreditation according Regulation 765/2008 in relation to CE marking of products, ref. No. (82) in the Whereas.
8	Directive 2014/25/EU	Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC	the Internal Market and Services	Link to Document			Where contracting authorities require the submission of certificates drawn up by a specific conformity assessment body, certificates from equivalent other conformity assessment bodies shall also be accepted by the contracting authorities. A conformity assessment body shall be a body that performs conformity assessment activities including calibration, testing, certification and inspection accredited in accordance with 765/2008, ref. Article 62.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
9	Directive 2009/81/EC	Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC	Internal Market and Services	Link to Document Link to summary			Member States may introduce voluntary accreditation schemes, ref. Whereas (59) and Article 36, 5.c. If the contracting authority/entity require the production of certificates drawn up by independent accredited bodies attesting the compliance of the economic operator with certain quality management systems standards, contracting authorities/entities shall refer to quality management systems based on the relevant European standards certified by independent accredited bodies conforming to the European standards concerning accreditation and certification.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
10	Regulation (EU, Euratom) 2018/1046	Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012	Budget	Link to Document Link to summary			In purchase the contracting authority may require that economic operators provide a test report or a certificate as means of proof of conformity with the procurement documents from a CAB accredited in accordance with Regulation 765/2008, ref. Annex 1, Section 2, 17.6 & 20.4.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
11	Directive 2006/123/EC	Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market	Internal Market and Services	Link to Document Link to summary			Policy on quality of services, ref. Article 26: Member States shall, in cooperation with the Commission, take accompanying measures to encourage providers to take action on a voluntary basis in order to ensure the quality of service provision, through certification or assessment of their activities by independent or accredited bodies.

2 UNION HARMONISATION LEGISLATIONS

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Directive 92/42/ECC	Directive 92/42/EEC Boiler efficiency directive	Energy	Link to Document Link to summary		X	Minimum criteria for Notified Bodies in Annex V. Conformity assessment procedures in other Annexes. No requirement or mentioning of accreditation.
2	Directive 2000/14/EC	Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors	Environment	Link to Document Link to summary		X	Minimum criteria for Notified Bodies in Annex IX. Conformity assessment procedures in other Annexes. No requirement or mentioning of accreditation.
3	Regulation (EU) 305/2011	Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC	Enterprise and Industry	Link to Document Link to summary		X	CPR Systems on the assessment and verification of constancy of performance procedures are set out in Annex V.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
4	Directive 2014/32/EU	Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast)	Enterprise and Industry	Link to Document Link to summary Corrigendum to Directive 2014/32/EU	X	X	MID Conformity assessment procedures set out in Annex II. In-house bodies shall be accredited.
5	Regulation (EU) 2016/426	Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC	Internal Market, Industry, Entrepreneurship and SMEs	Link to Document Link to summary		X	Conformity assessment procedures set out in Annex III.
6	Regulation (EU) 2016/425	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC	Enterprise and Industry	Link to Document Link to summary		X	PPE Conformity assessment procedures set out in Article 19 & Annexes.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
7	Directive 2014/68/EU	Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment	Enterprise and Industry	Link to Document Link to summary		X	PED Conformity assessment procedures set out in Article 14 & Annexes.
8	Directive 2014/53/EU	Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC	Enterprise and Industry	Link to Document Link to summary		X	RED Conformity assessment procedures set out in Article 17 & Annexes.
9	Directive 2014/28/EU	Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast)	Enterprise and Industry	Link to Document Link to summary		X	EXPLOSIVES Conformity assessment procedures set out in Article 20 & Annex III.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
10	Directive 2014/30/EU	Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)	Enterprise and Industry	Link to Document Link to summary		X	EMC Conformity assessment procedures set out in Article 14 & Annexes
11	Directive 2014/34/EU	Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)	Enterprise and Industry	Link to Document Link to summary		X	ATEX Conformity assessment procedures set out in Article 13 & Annexes
12	Directive 2014/29/EU	Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels	Enterprise and Industry	Link to Document Link to summary		X	SPVD Conformity assessment procedures set out in Article 13 & Annex II

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
13	Directive 2014/33/EU	Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts	Enterprise and Industry	Link to Document Link to summary		X	LIFT Conformity assessment procedures set out in Article 15 for safety components for lifts and Article 16 for lifts and for both in Annexes.
14	Directive 2014/31/EU	Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments	Enterprise and Industry	Link to Document Link to summary		X	NAWI Accreditation according to 765/2008 of CAB's as basis for CAB to become Notified Body. Conformity assessment procedures set out in Article 13 & Annex II
15	Directive 2013/29/EU	Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast)	Enterprise and Industry	Link to Document Link to summary		X	PAD Conformity assessment procedures set out in Article 17 & Annex II

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
16	Directive 2014/90/EU	Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC	Mobility and Transport	Link to Document Link to summary Corrigendum to Directive 2014/90/EU		X	MED Conformity assessment procedures set out in Article 15 & Annex II
17	Directive 2013/53/EU	Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC	Enterprise and Industry	Link to Document Link to summary		X	RCD Conformity assessment procedures set out in Chapter IV, with reference to Modules in Decision 768/2008, Annex II.
18	Directive 2010/35/EU	Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC	Energy and Transport	Link to Document Link to summary		X	TPED Conformity assessment requirements, ref. Article 12 where ref. to Annexes to Directive 2008/68/EC and in Chapters 3 and 4 are mentioned. Requirements for CAB's also in ADR.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
19	Directive 2009/48/EC	Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys	Enterprise and Industry	Link to Document Link to summary		X	TOYS Conformity assessment procedures, ref. Article 19 and Annex II. Requirements for CAB's in Article 26.
20	Regulation (EU) 2016/424	Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC	Internal Market, Industry, Entrepreneurship and SMEs	Link to Document Link to summary		X	Conformity assessment procedures set out in Annexes to the Regulation.
21	Regulation (EU) 2019/1009	Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003	Internal Market, Industry, Entrepreneurship and SMEs	Link to Document		X	Conformity assessment procedures set out in Article 15 & Annex IV.
22	Directive 2006/42/EC	Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)	Enterprise and Industry	Link to Document Link to summary		X	Criteria for Notified Bodies in Annex XI. No mentioning of accreditation. Conformity assessment procedures, ref. Article 12.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
23	2009/750/EC: Commission Decision	2009/750/EC: Commission Decision of 6 October 2009 on the definition of the European Electronic Toll Service and its technical elements	Enterprise and Industry	Link to Document		X	Minimum criteria for Notified Body in Annex V, include accreditation. Commission Decision 2009/750 end of validity 18/10/2021, repealed by Commission Implementing Regulation (EU) 2020/204.
24	Directive (EU) 2016/797	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union	Mobility and Transport	Link to Document Link to summary		X	Requirements for CAB's in Chapter VI, Article 30 to 35.
25	Directive 2008/57/EC	Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (Recast)	Energy and Transport	Link to Document Link to summary		X	Criteria for Notified Bodies in Annex VIII. No mentioning of accreditation.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
26	Regulation (EC) No 552/2004	Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation)	Energy and Transport	Link to Document Link to summary		X	Regulation 552/2004 is repealed by Regulation (EU) 2018/1139, where Notified Bodies are mentioned. Accreditation is referred to be done by 'The Agency or the national competent authority or authorities'.
27	Regulation (EU) 2019/945	Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems	Mobility and Transport	Link to Document		X	Accreditation as basis for CAB to become Notified Body, ref. Article 25, 2. Accreditation is defined in Article 3 (9) referring to 765/2008. Conformity assessment procedures, ref. Article 13.
28	Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	Health and Consumers	Link to Document Link to summary		X	Documentation for accreditation according to 765/2008 may be submitted as part of the application to become Notified Body, ref. Article 38.2.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
29	Regulation (EU) 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	Health and Consumers	Link to Document Link to summary		X	Documentation for accreditation according to 765/2008 may be submitted as part of the application to become Notified Body, ref. Article 34.2. Conformity assessment procedures, ref. Annexes IX to XI. Furthermore, Article 5 refers to ISO 15189 and accreditation.
30	Council Directive 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	Health and Consumers	Link to Document Link to summary		X	Criteria for Notified Bodies in Annex XI. No mentioning of accreditation.
31	Council Directive 90/385/EEC	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices	Industry	Link to Document Link to summary		X	Annex 8 Minimum criteria to be met when designating Inspection Bodies to be notified.
32	Directive 98/79/EC	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices	Industry	Link to Document Link to summary		X	Annex IX Criteria for the designation of notified Bodies

3 FOOD AND FEED

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	COM (2014) 179	Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Action Plan for the future of Organic Production in the European Union	Agriculture and Rural Development	Link to Document Link to summary		X	Communication from the Commission on future activities. Action 9 & 10 addresses accreditation as an instrument to demonstrate technical competence. Further also encouragement to Member States to explore synergy and simplification between AB's and Authorities.
2	Regulation (EU) 1306/2013	Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008	Agriculture and Rural Development	Link to Document Link to summary		X	Accreditation of Paying Agencies and other Bodies, however not in the sense of accreditation according to 765/2008. Certification Bodies shall have the necessary technical competence ref. Art. 9, however no reference to accreditation of certification bodies.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
3	Regulation (EU) 2018/848	Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007	Agriculture and Rural Development	Link to Document Link to summary	X		Control bodies shall be accredited under the relevant harmonised standard for 'Conformity assessment – Requirements for bodies certifying products, processes and services',

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
4	Regulation (EU) 2017/625	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, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)	Health and Consumers	Link to Document Link to summary		X	<p>Accreditation of Delegated bodies according to 17020, ref. Article 29 (b)(iv) and Laboratories according to 17025, ref. Article 37(2)(e). Derogations from mandatory accreditation are laid down in Articles 41 and 42.</p> <p>Article 93 refer to accreditation of EU reference laboratories. The regulation lay down amendments to other Regulations where accreditation is mentioned:</p> <ul style="list-style-type: none"> – Regulation (EU) No 1151/2012, Article 39 concerning Delegated Bodies performing controls in third countries. <p>Regulation (EU) No 652/2014, where Article 30a is inserted concerning accreditation of national reference laboratories for plant health.</p>

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
5	Regulation (EU) 1151/2012	Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs	Agriculture and Rural Development	Link to Document Link to summary	X		Accreditation of Control Bodies for Product certification, ref. Article 39.
6	Regulation (EU) 251/2014	Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and repealing Council Regulation (EEC) No 1601/91	Agriculture and Rural Development	Link to Document Link to summary	X		Verification of compliance with specification to be performed by control bodies and certification bodies accredited according to 17065, ref. Article 23, 1(b) & 2(b).
7	Regulation (EC) 2003/2003	Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers	Enterprise and Industry	Link to Document Link to summary	X		Accreditation of Laboratories, Annex I. Regulation 2003/2003 is repealed with effect from 16 July 2022 by Regulation (EU) 2019/1009.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
8	Regulation (EU) 2019/787	Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008	Agriculture and Rural Development	Link to Document Link to summary	X		Control Bodies and product certification bodies shall be accredited according to 17065, ref. Article 38, 5.
9	Commission Regulation (EC) 1020/2009	Commission Regulation (EC) No 1020/2009 of 28 October 2009 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I, III, IV and V thereto to technical progress	Agriculture and Rural Development	Link to Document	X		Amending Regulation 2003/2003, requirement for accredited laboratories, ref. Annex IV.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
10	Commission Regulation (EC) 1981/2006	Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms	Agriculture and Rural Development	Link to Document Commission Implementing Regulation (EU) No 120/2014	X		Requirement for accredited laboratories, amended in Commission Implementing Regulation (EU) No 120/2014, ref. Annex I.
11	Commission Regulation (EU) 2017/644	Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014	Health and Food Safety	Link to Document	X		Laboratories shall be accredited, however no reference to 765/2008, Ref. Annex III, 4 & Annex IV, 7.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
12	Commission Regulation (EU) 142/2011	Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive	Health and Food Safety	Link to Document	X		Processing plants must use an accredited laboratory, either internal or external, ref. Annex IV, Section 1, 5 and Annex V Section 1, 4 and 2, 4. No reference to 765/2008.
13	Commission Regulation (EC) 152/2009	Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed	Health and Food Safety	Link to Document Commission Regulation (EU) 2017/771	X		Laboratories shall be accredited according to 17025, ref. Annex V, section B II, 4. No reference to 765/2008. Amended by Commission Regulation (EU) 2017/771 as regards the methods for the determination of the levels of dioxins and polychlorinated biphenyls

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
14	Commission Regulation (EC) 566/2008	Commission Regulation (EC) No 566/2008 of 18 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing of the meat of bovine animals aged 12 months or less	Health and Food Safety	Link to Document	X		Where the competent authority delegates its check tasks to independent third-party bodies, these shall be accredited to 17065, ref. Article 6, (b) and Article 7, 2.
15	Council Regulation (EC) 491/2009	Council Regulation (EC) No 491/2009 of 25 May 2009 amending Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)	Agriculture and Rural Development	Link to Document	X		Product certification Bodies who verify compliance with specifications shall be accredited. No reference to 765/2008.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
16	Commission Delegated Regulation (EU) 2018/273	Commission Delegated Regulation (EU) 2018/273 of 11 December 2017 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the scheme of authorisations for vine plantings, the vineyard register, accompanying documents and certification, the inward and outward register, compulsory declarations, notifications and publication of notified information, and supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the relevant checks and penalties, amending Commission Regulations (EC) No 555/2008, (EC) No 606/2009 and (EC) No 607/2009 and repealing Commission Regulation (EC) No 436/2009 and Commission Delegated Regulation (EU) 2015/560	Agriculture and Rural Development	Link to Document	X		Certification by accredited CABs, ref. Annex II, B. (2). Reference to 765/2008.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
17	Commission Implementing Regulation (EU) No 392/2013	Commission Implementing Regulation (EU) No 392/2013 of 29 April 2013 amending Regulation (EC) No 889/2008 as regards the control system for organic production	Agriculture and Rural Development	Link to Document		X	Accreditation to be taken into account by competent authorities when supervising control bodies, ref. Articles 92c & 92e.

4 CLIMATE / ENVIRONMENT

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Directive (EU) 2018/410	Directive (EU) 2018/410 of the European Parliament and of the Council of 14 March 2018 amending Directive 2003/87/EC to enhance cost-effective emission reductions and low-carbon investments, and Decision (EU) 2015/1814	Climate Action	Link to Document	X		EU ETS Accreditation amended by amending Article 15 in 2003/87/EC.
2	Commission Implementing Regulation (EU) 2018/2067	Commission Implementing Regulation (EU) 2018/2067 of 19 December 2018 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council	Climate Action	Link to Document	X		EU ETS Accreditation of verifiers according to 765/2008.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
3	Commission Regulation (EU) 601/2012	Commission Regulation (EU) No 601/2012 of 21 June 2012 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council	Climate Action	Link to Document	X		EU ETS Requirement for the use of accredited laboratories, ref. Article 34, 1.
4	Commission Delegated Regulation (EU) 2019/331	Commission Delegated Regulation (EU) 2019/331 of 19 December 2018 determining transitional Union-wide rules for harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC of the European Parliament and of the Council	Climate Action	Link to Document	X		EU ETS Accreditation mentioned in Annex IV regarding identification of the verifier.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
5	Commission Delegated Regulation (EU) 2019/1603	Commission Delegated Regulation (EU) 2019/1603 of 18 July 2019 supplementing Directive 2003/87/EC of the European Parliament and of the Council as regards measures adopted by the International Civil Aviation Organisation for the monitoring, reporting and verification of aviation emissions for the purpose of implementing a global market-based measure	Climate Action	Link to Document	X		EU ETS Accreditation of verifiers carrying out that verification shall be subject to the same requirements as those laid down in Article 15 of Directive 2003/87/EC and Part B of Annex V to that Directive, as well as Implementing Regulation (EU) 2018/2067.
6	Regulation (EU) 2015/757	Regulation (EU) 2015/757 of the European Parliament and of the Council of 29 April 2015 on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport, and amending Directive 2009/16/EC	Climate Action	Link to Document Link to summary	X		EU MRV Maritime. Accreditation of verifiers according to 765/2008. Chapter III Verification and Accreditation

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
7	Commission Delegated Regulation (EU) 2016/2072	Commission Delegated Regulation (EU) 2016/2072 of 22 September 2016 on the verification activities and accreditation of verifiers pursuant to Regulation (EU) 2015/757 of the European Parliament and of the Council on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport	Climate Action	Link to Document	X		EU MRV Maritime. Accreditation of verifiers according to 765/2008. Accreditation of verifiers in Chapter IV and requirements for NABs in Chapter V.
8	Council Directive (EU) 2015/652	Council Directive (EU) 2015/652 of 20 April 2015 laying down calculation methods and reporting requirements pursuant to Directive 98/70/EC of the European Parliament and of the Council relating to the quality of petrol and diesel fuels	Climate Action	Link to Document	X		Methods for estimating Upstream emission reduction must be verified by an accredited verifier in accordance with ISO 14065, ref. Annex I, part1, 3(d)(ii). Reference is stated to Regulation 600/2012.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
9	Regulation (EC) 1221/2009	Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC	Environment	Link to Document Link to summary		X	EMAS One of the means to be an Environmental verifier is to be a conformity assessment body which is accredited according to this regulation, see definition in Article 2 (20).

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
10	Commission Decision (EU) 2017/2285	Commission Decision (EU) 2017/2285 of 6 December 2017 Amending the user's guide setting out the steps needed to participate in EMAS, under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)	Environment	Link to Document		X	EMAS Accreditation of verifiers according to 765/2008 is one option to act as environmental verifier.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
11	Commission Regulation (EU) 2018/2026	Commission Regulation (EU) 2018/2026 of 19 December 2018 amending Annex IV to Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)	Environment	Link to Document		X	EMAS Accredited environmental verifiers as in Regulation 1221/2009.
12	Commission Decision (EU) 2018/1702	Commission Decision (EU) 2018/1702 of 8 November 2018 establishing the EU Ecolabel criteria for lubricants	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories (17025) and CAB's for product certification, ref. Annex, section Assessment and verification.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
13	Commission Decision (EU) 2018/680	Commission Decision (EU) 2018/680 of 2 May 2018 establishing EU Ecolabel criteria for indoor cleaning services	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories and CAB's for product certification, ref. Annex, section Assessment and verification.
14	Commission Decision (EU) 2017/1214	Commission Decision (EU) 2017/1214 of 23 June 2017 establishing the EU Ecolabel criteria for hand dishwashing detergents	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories and CAB's for product certification, ref. Annex, section Assessment and verification.
15	Commission Decision (EU) 2017/1216	Commission Decision (EU) 2017/1216 of 23 June 2017 establishing the EU Ecolabel criteria for dishwasher detergents	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories and CAB's for product certification, ref. Annex, section Assessment and verification.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
16	Commission Decision (EU) 2017/1215	Commission Decision (EU) 2017/1215 of 23 June 2017 establishing the EU Ecolabel criteria for industrial and institutional dishwasher detergents	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories and CAB's for product certification, ref. Annex, section Assessment and verification.
17	Commission Decision (EU) 2017/1219	Commission Decision (EU) 2017/1219 of 23 June 2017 establishing the EU Ecolabel criteria for industrial and institutional laundry detergents	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories and CAB's for product certification, ref. Annex, section Assessment and verification.
18	Commission Decision (EU) 2017/1218	Commission Decision (EU) 2017/1218 of 23 June 2017 establishing the EU Ecolabel criteria for laundry detergents	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories and CAB's for product certification, ref. Annex, section Assessment and verification.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
19	Regulation (EC) 648/2004	Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents	Enterprise and Industry	Link to Document Link to summary		X	Accreditation of Laboratories, Annex I.
20	Commission Decision (EU) 2017/1217	Commission Decision (EU) 2017/1217 of 23 June 2017 establishing the EU Ecolabel criteria for hard surface cleaning products	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited according to 765/2008, Laboratories and CAB's for product certification, ref. Annex, section Assessment and verification.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
21	Commission Decision (EU) 2019/70	Commission Decision (EU) 2019/70 of 11 January 2019 establishing the EU Ecolabel criteria for graphic paper and the EU Ecolabel criteria for tissue paper and tissue products	Environment	Link to Document		X	Competent bodies shall preferentially recognise attestations which are issued by bodies accredited, Laboratories and CAB's for product certification, ref. Annex I and II. No reference to 765/2008. Certification bodies issuing forest and/or chain of custody certificates shall be accredited or recognised by that certification scheme, ref. Annex II, criterion 3.
22	Directive 2012/27/EU	Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC	Energy	Link to Document Link to summary	X		State the Member State obligation to establish accreditation and certification schemes, ref. article 16.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
23	Directive (EU) 2018/2001	Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources	Energy	Link to Document Link to summary		X	Member States encouraged to contribute towards ensuring the correct implementation of the certification principles of voluntary schemes by supervising the operation of certification bodies that are accredited by the national accreditation body. However, no reference to 765/2008.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
24	Regulation (EU) 2018/1999	Regulation (EU) 2018/1999 of the European Parliament and of the Council of 11 December 2018 on the Governance of the Energy Union and Climate Action, amending Regulations (EC) No 663/2009 and (EC) No 715/2009 of the European Parliament and of the Council, Directives 94/22/EC, 98/70/EC, 2009/31/EC, 2009/73/EC, 2010/31/EU, 2012/27/EU and 2013/30/EU of the European Parliament and of the Council, Council Directives 2009/119/EC and (EU) 2015/652 and repealing Regulation (EU) No 525/2013 of the European Parliament and of the Council	Energy	Link to Document Link to summary		X	Accreditation mentioned in relation reporting on e.g. robustness of voluntary schemes and criteria for accreditation. However, no reference to 765/2008.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
25	Directive 2009/125/EC	Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of eco design requirements for energy-related products	Enterprise and Industry	Link to Document Link to summary		X	Article 8 refer to Conformity assessment procedure based on Modules in 768/2008, Annex II.
26	Regulation (EU) 517/2014	Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006	Climate Action	Link to Document Link to summary	X		Accredited auditor required, ref. Article 14, 2(a) & 19, 6(a). Accreditation pursuant Directive 2003/87/EC (EU ETS).
27	Regulation (EC) 66/2010	Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel	Environment	Link to Document Link to summary		X	Competent bodies shall preferentially recognise tests which are accredited according to ISO 17025 and verifications performed by bodies which are accredited under the EN 45011 standard or an equivalent international standard, ref. Article 9, 7.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
28	Council Regulation (EU) No 333/2011	Council Regulation (EU) No 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council	Environment	Link to Document	X		Management system of a producer to be verified for compliance by an accredited CAB (as defined in 765/2008) or an accredited environmental verifier, ref. Article 6, 5.
29	Commission Regulation (EU) No 715/2013	Commission Regulation (EU) No 715/2013 of 25 July 2013 establishing criteria determining when copper scrap ceases to be waste under Directive 2008/98/EC of the European Parliament and of the Council	Environment	Link to Document	X		Management system of a producer to be verified for compliance by an accredited CAB (as defined in 765/2008) or an accredited environmental verifier, ref. Article 5, 5.
30	Commission Regulation (EU) No 1179/2012	Commission Regulation (EU) No 1179/2012 of 10 December 2012 establishing criteria determining when glass cullet ceases to be waste under Directive 2008/98/EC of the European Parliament and of the Council	Environment	Link to Document	X		Management system of a producer to be verified for compliance by an accredited CAB (as defined in 765/2008) or an accredited environmental verifier, ref. Article 5, 5.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
31	Commission Regulation (EU) 2016/631	Commission Regulation (EU) 2016/631 of 14 April 2016 establishing a network code on requirements for grid connection of generators	Energy	Link to Document	X		“Authorised Certifiers” who issues equipment certificates shall be accredited by NAB in accordance with 765/2008.
32	Commission Directive (EU) 2015/1480	Commission Directive (EU) 2015/1480 of 28 August 2015 amending several annexes to Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council laying down the rules concerning reference methods, data validation and location of sampling points for the assessment of ambient air quality	Environment	Link to Document	X		Accreditation of CABs according to 765/2008, ref. Article 3. National reference laboratories shall be accredited, ref. Annex II.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
33	Commission Directive 2009/90/EC	Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status	Environment	Link to Document		X	Accredited organisations mentioned in Article 6, as well of laboratories complying with ISO 17025.
34	Directive 2008/50/EC	Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe	Environment	Link to Document	X		National laboratories, when appointed by the appropriate competent authority shall be accredited according to EN/ISO 17025 by

5 VEHICLES

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Directive (EU) 2019/520	Directive (EU) 2019/520 of the European Parliament and of the Council of 19 March 2019 on the interoperability of electronic road toll systems and facilitating cross-border exchange of information on the failure to pay road fees in the Union	Mobility and Transport	Link to Document Link to summary		X	Deadline for adoption by Member States is 19 October 2021. Mention accreditation but no reference to 765/2008. EETS (European Electronic Toll Service Providers) shall be accredited, however one requirement is ISO 9001 or equivalent. Notified Bodies are mentioned.
2	Directive 2007/46/EC	Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)	Enterprise and Industry	Link to Document Link to summary		X	Accreditation Body may act on behalf of a Competent Authority, ref. Article 3, 30. Accreditation mentioned in Article 42, 1.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
3	Regulation (EU) 2018/858	Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC	Internal Market, Industry, Entrepreneurship and SMEs	Link to Document Link to summary	X		Accreditation of CAB's in relation to Technical Services and in-house technical services, ref. Chapter XV, Article 72, 2(a).
4	Regulation (EU) No 168/2013	Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles	Enterprise and Industry	Link to Document Link to summary	X		Accreditation of in-house technical services of the manufacturer, ref. Article 64. Accreditation of in-house technical services only for Category A as stated in Article 63. Accreditation of technical services, ref. Article 66.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
5	Regulation (EU) No 167/2013	Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles	Enterprise and Industry	Link to Document Link to summary	X		Accreditation of in-house technical services of the manufacturer, ref. Article 60. Accreditation of in-house technical services only for Category A as stated in Article 59. Accreditation of technical services, ref. Article 62.

6 RAILWAY

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Technical document	Requirements for Conformity Assessment Bodies seeking notification	ERA	Link to Document Link to summary		X	Mandatory document for the assessment of Notified Bodies to Directive (EU) 2016/797. See above 2.25
2	Regulation (EU) 2016/796	Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004	Mobility and Transport	Link to Document Link to summary		X	Accreditation of Laboratories according to 765/2008, ref. Art. 32. Monitoring of notified conformity assessment bodies mentioned in Article 34.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
3	Commission Regulation (EU) 445/2011	Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007	Mobility and Transport	Link to Document		X	CABs to be accredited by Nab according to 765/2008, ref. Whereas (10), Article 3, 2(a) & 6, 2. Criteria for accreditation or recognition of certification bodies involved in the assessment and award of ECM certificates, ref. Annex II. Regulation (EU) No 445/2011 is repealed with effect from 16 June 2020, ref. Commission Implementing Regulation (EU) 2019/779.
4	Commission Implementing Regulation (EU) 402/2013	Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	Mobility and Transport	Link to Document		X	One of three options is that CAB is to be accredited according to 17020, ref. Article 7 and Annex II. Accreditation and conformity assessment defined according to 765/2008, ref. Article 3, (28), (29) & (30).

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
5	Directive (EU) 2016/798	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety	Mobility and Transport	Link to Document Link to summary		X	Accreditation mentioned in relation to CABs certifying entities in charge of maintenance as an option. No reference to 765/2008.
6	Commission Implementing Regulation (EU) 2019/779	Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011	Mobility and Transport	Link to Document		X	Accreditation as defined in 765/2008 of CABs certifying entities in charge of maintenance.

7 TRANSPORT

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Regulation (EU) 912/2010	Regulation (EU) No 912/2010 of the European Parliament and of the Council of 22 September 2010 setting up the European GNSS Agency, repealing Council Regulation (EC) No 1321/2004 on the establishment of structures for the management of the European satellite radio navigation programmes and amending Regulation (EC) No 683/2008 of the European Parliament and of the Council	Energy and transport	Link to Document Link to summary		X	The Regulation mention accreditation referring to a Security Accreditation Board. No reference to 765/2008.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
2	Directive 2007/59/EC	Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community	Energy and Transport	Link to Document Link to summary		X	The Regulation opens for accreditation of persons or bodies, ref. Article 20, if the Member State do not set up a recognition scheme by an Authority.
3	Directive 2014/45/EU	Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC	Mobility and Transport	Link to Document Link to summary		X	Accreditation according to 765/2008 of Testing Centres is a possibility, ref. Article 14, 4. National requirements may decide on the use of accreditation of Testing Centres.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
4	Regulation (EU) No 165/2014	Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport, repealing Council Regulation (EEC) No 3821/85 on recording equipment in road transport and amending Regulation (EC) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport	Mobility and Transport	Link to Document Link to summary		X	Accreditation only mentioned in the references. In the Whereas (15) is stated: Nothing in this Regulation prevents Member States from ensuring their approval, control and certification through the procedures laid down in Regulation 765/2008, provided that the minimum criteria set out in this Regulation are fulfilled.
5	Directive 2010/40/EU	Directive 2010/40/EU of the European Parliament and of the Council of 7 July 2010 on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport	Mobility and Transport	Link to Document Link to summary		X	Conformity assessment in accordance with Decision 768/2008, ref. Article 6, 6.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
6	Regulation (EU) 2016/1628	Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC	Mobility and Transport	Link to Document Link to summary		X	Accreditation is one option for Technical Service to demonstrate compliance, ref. Article 49.

8 AVIATION

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Commission Implementing Regulation (EU) 2015/1998	Commission Implementing Regulation (EU) 2015/1998 of 5 November 2015 laying down detailed measures for the implementation of the common basic standards on aviation security	Mobility and Transport	Link to Document		X	NABs established pursuant to 765/2008 may be empowered to accredit the conformity assessment capacity of legal entities to perform EU aviation security validation, ref. 11.6.3

9 FORENSIC

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Council framework Decision 2009/905/JHA	Council framework Decision 2009/905/JHA of 30 November 2009 on Accreditation of forensic service providers carrying out laboratory activities	Justice	Link to Document	X		Forensic service providers (Laboratories) shall be accredited, ref. Article 4.

10 DATA PROTECTION

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Regulation (EU) 2016/679	Regulation (EU) 2016/679 of the European Parliament and of 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, and repealing Directive 95/46/EC (General Data Protection Regulation)	Justice	Link to Document Link to summary Corrigendum to Regulation (EU) 2016/679		X	GDPR Accreditation according to 765/2008 of Certification Bodies in accordance with 17065 is one option. Another option involves a competent supervisory authority.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
2	Commission Implementing Regulation (EU) 2015/1502	Commission Implementing Regulation (EU) 2015/1502 of 8 September 2015 on setting out minimum technical specifications and procedures for assurance levels for electronic identification means pursuant to Article 8(3) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market	Justice	Link to Document		X	Conformity Assessment Bodies as defined in 765/2008 mentioned in Annex, section 2.1.2 & 2.1.3.

11 CYBERSECURITY / IT SECURITY

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Regulation (EU) 2019/881	Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act)	Communications Networks, Content and Technology	Link to Document	X		European cybersecurity certification scheme for Information, Communication and Technology is to be established. Accreditation of CAB's is defined. Requirements for CAB's in Article 60 and in the Annex to the Regulation. The European Union Agency for Network and Information Security (ENISA), has an important role in setting up the certification scheme and establishing co-operation and information.

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
2	Regulation (EU) 910/2014	Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC	Information Society and Media	Link to Document Link to summary	X		Accreditation according to 765/2008 of a CAB to carry out conformity assessment of a qualified trust service provider and the qualified trust services it provides.

12. MEDICAL

No	EU legislation number	EU legislation / scheme full title	Responsible EU Commission Department (DG)	Source/Link(s)	Accreditation		Comments
					Mandatory	Voluntary	
1	Commission Implementing Regulation (EU) 920/2013	Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices	Health and Consumers	Link to Document		X	Accreditation may be used by Designating National Authority as basis for appointing CAB to be Notified Body, ref. Whereas (11). Accreditation defined in Article 1, (d).