



EU Regulation relevant to metrology

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Introduction

The EMPIR normative call scope for 2018 includes a strand on research to support regulation. Specifically, it says:

The overall strategic aim of the Targeted Programme (TP) “Pre- and co-normative research” is to develop metrological methods and techniques required for standardisation, regulation and conformity assessment. Proposed topics should address one of the following strands:

.....

3. Specific documented demands of European Regulators and Conformity Assessment bodies for metrological research in any area. Proposals may address the development of traceable measurement methods or the provision of validated data sets, which are required for these purposes. It is expected that projects selected for funding will have fewer partners and lower eligible costs than Joint Research Projects selected under other TP calls (e.g. industry, health, energy or environment).

To inform stage 1 of the call, EURAMET has been collecting information from its members on European Regulations that require support from the metrology infrastructure. Those identified so far are listed in Table 1. A subset of these already have needs for research identified and some are the subject of existing JRPs. These are listed in Table 2.

Authors of Potential Research Topics are requested to consider this information in the development of their PRTs.

	Reference	Name of Regulation/ General topic	NMI/DI ¹ Interest
1	2014/32/EU NLF (New Approach) Directive	Measuring instruments (MID) Directive covering 10 different measuring instruments The harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast).	INRIM,LNE, PTB, CEM, RISE, JV, BEV, MIRS, CMI, BFKH, GUM, AS Metrosert, BIM, LNMC, SMU, (METAS 2) Lithuanian Energy Institute Laboratory of Heat-Equipment Research and Testing (LEI) SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - (MIRS-SIQ) National Measurement and Regulation Office (NMO) Slovenska Legalna Metrologia n.o. (SLM) BRML(INM)
2	2014/31/EU NLF (New Approach) Directive	Non-automatic weighing instruments (NAWID) The harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.	LNE, PTB, CEM, RISE, JV, BEV, ILNA, CMI, MIRS, FTMC, GUM, Metrosert, BIM, LNMC, SMU, BFKH, (METAS) NMO (a part of Regulatory Delivery) FORCE Certification A/S VILNIUS METROLOGY CENTRE (VMC) Slovenska Legalna Metrologia n.o. (SLM) BRML(INM)

3	<p>75/106/EEC, 76/211/EEC, 2007/45/EC (amending Council Directive 76/211/EEC)</p> <p>2009/34/EC Directive</p>	<p>Prepackaging (making-up by volume of certain prepackaged liquids; making-up by weight or by volume of certain prepackaged products; nominal quantities for prepacked products; measuring instruments and methods of metrological control) /</p> <p>The harmonisation of the laws of the Member States relating prepackaging.</p>	All member states
4	<p>2017/745/EU (repealing 93/42/EEC) New Approach Regulation</p> <p>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</p>	<p>Medical devices (MD) /</p> <p>This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other.</p>	NSAI, RISE, LNE (G-MED), VTT, INRIM, VSL, SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - (SIQ), TÜBİTAK UME Medical Metrology Laboratory

5	<p>Regulation 2017/745 (repealing Directive 90/385/EEC on Active Implantable Medical Devices)</p> <p>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</p>	<p>Medical devices: activeimplantable/</p> <p>The approximation of the laws of the Member States relating to active implantable medical devices</p>	NSAI, LNE (G-MED) INRIM
6	<p>2017/746/EU (repealing 98/79/EC) New Approach Regulation</p>	<p>In.vitro diagnostic (IVD)/</p> <p>This Regulation aims to ensure the smooth functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for in vitro diagnostic medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other.</p>	PTB, NSAI, LNE (G-MED), VTT, INRIM, LGC
7	<p>2014/30/EU NLF (New Approach) Directive</p>	<p>Electromagnetic compatability (EMC) (recast) /</p> <p>The harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)</p>	<p>LNE, RISE, LNMC, PTB, VSL, FORCE Certification A/S LABORATORIO CENTRAL OFICIAL DE ELECTROTECNIA (LCOE) INTA - Instituto Nacional de Tecnologia Aeroespacial</p>

8	Directive 2014/53/EU (repealing Directive 1999/5/EC)	Radio Equipment Directive (RED) relating to the making available on the market of radio equipment	RISE, CMI FORCE Certification A/S SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ
9	2006/42/EC New Approach Directive	Machinery (MD)/ Approximation of the laws of the Member States relating to machinery and amending Directive 95/16/EC (recast)	PTB, RISE, VTT SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ
10	2014/34/EU NLF (New Approach) Directive	Equipment for explosive atmospheres (ATEX) / The harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)	PTB, RISE, VTT Bundesanstalt für Materialforschung und –prüfung (BAM) SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ
11	89/686/EEC New Approach Directive Regulation 2016/425 applicable as of 21 April 2018	Personal protective equipment (PPE)/ The approximation of the laws of the Member States relating to personal protective equipment	LNE-IRSN, RISE
12	2009/125/EC New Approach Directive	Ecodesign and energy labelling/ Establishing a framework for the setting of ecodesign requirements for energy-related products (recast)	PTB, INRIM, VSL

13	2010/35/EU NLF Directive	Transportable pressure equipment/ In order to enhance safety with regard to transportable pressure equipment approved for the inland transport of dangerous goods and to ensure free movement, including placing on the market, making available on the market and use of such transportable pressure equipment within the Union, it is necessary to lay down detailed rules concerning the obligations of the various operators and the requirements to be fulfilled by the equipment concerned.	BAM, RISE
14	2016/426/EU Regulation	Appliances burning gaseous fuels	RISE
15	2014/65/EU Directive	Markets in Financial Instruments Directive (MiFID II)/ The purpose of this Directive is to cover undertakings the regular occupation or business of which is to provide investment services and/or perform investment activities on a professional basis. Its scope should therefore not cover any person with a different professional activity.	VSL, NMIs whose data are evaluated by BIPM for contributions to International Atomic Time
16	1907/2006/EC New Approach Regulation	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in mixtures and in articles, while enhancing competitiveness and innovation.	

17	2009/244/EC 2009/245/EC 2012/1194/EU 2015/1428/EU Regulation	Lamps, LEDs, OLEDs (ecodesign requirements for non-directional household lamps; ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps, and repealing Directive 2000/55/EC; ecodesign requirements for directional lamps, light emitting diode lamps and related equipment; non-directional household lamps and Commission Regulation (EC) No 245/2009 with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps and repealing Directive 2000/55/EC of the European Parliament and of the Council and Commission Regulation (EU) No 1194/2012 with regard to ecodesign requirements for directional lamps, light emitting diode lamps and related equipment)	NIMs involved in Photometry
18	2014/94/EU Directive	Deployment of alternative fuels infrastructure	PTB, VSL
19	2012/27/EU Directive EED	Energy efficiency/ The Union is facing unprecedented challenges resulting from increased dependence on energy imports and scarce energy resources, and the need to limit climate change and to overcome the economic crisis. Energy efficiency is a valuable means to address these challenges. It improves the Union's security of supply by reducing primary energy consumption and decreasing energy imports. It helps to reduce greenhouse gas emissions in a cost- effective way and thereby to mitigate climate change. Shifting to a more energy efficient economy should also accelerate the spread of innovative technological solutions and improve the competitiveness of industry in the Union, boosting economic growth and creating high quality jobs in several sectors related to energy efficiency.	PTB, INRIM, RISE, VSL

20	1194/2012/EU (244/2009/EC, 245/2009/EC)	Ecodesign Regulations on Lighting	NMIs involved in photometric measurements
21	<p>2013/59/Euratom Directive</p> <ul style="list-style-type: none"> - StrVG – Strahlenschutzvorsorgegesetz - Richtlinie zur Kontrolle der Eigenüberwachung radioaktiver Emissionen aus Kernkraftwerken - REI – Richtlinie zur Emissions- und Immissionsüberwachung kerntechnischer Anlagen - StrlSchV – Strahlenschutzverordnung - RöV – Röntgenverordnung –Qualitätssicherungsrichtlinie für die Röntgendiagnostik – Sachverständigen-Richtlinie Uusi säteilylaki (1.1.2018) <p>Verordnung des EJPD vom 7. Dezember 2012 über Messmittel für ionisierende Strahlung (StMmV, SR 941.210.5)</p>	<p>Basic Safety Standard/ Laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom</p>	PTB, BAM, VTT, STUK (Radiation and Nuclear Safety Authority Finland), METAS, VSL
22	2000/60/EC Directive	<p>Water Directive (framework for Community action in the field of water policy)/</p> <p>Establishing a framework for Community action in the field of water policy</p>	PTB, BAM, INRIM, LGC

23	2013/51/Euratom Directive	<p>Directive on protection against radioactive substances in drinking water/</p> <p>Establishing a framework for Community action in the field of water policy.</p>	PTB, RISE
24	98/83/EC Directive	<p>Directive on the quality of water intended for human consumption</p> <p>(Drinking Water Directive)/ Relating to the quality of water intended for human consumption (5) to scientific and technological progress.</p>	PTB, BAM, INRIM, LGC
25	2015/703/EC Regulation	<p>Commission Regulation on establishing a network code on interoperability and data exchange rules /</p> <p>The lack of harmonisation in technical, operational and communication areas could create barriers to the free flow of gas in the Union, thus hampering market integration. Union interoperability and data exchange rules should allow the necessary harmonisation in those areas, therefore leading to effective market integration. For that purpose and for facilitating commercial and operational cooperation between adjacent transmission system operators, this Regulation should address interconnection agreements, units, gas quality, odourisation and data exchange. It should provide rules and procedures to reach an appropriate level of harmonisation towards efficient gas trading and transport across gas transmission systems in the Union.</p>	PTB, RISE

26	882/2004/EC Regulation	Verification of compliance with feed and food law, animal health and animal welfare rules/ Feed and food should be safe and wholesome. Community legislation comprises a set of rules to ensure that this objective is attained. These rules extend to the production and the placing on the market of both feed and food.	BVL, INRIM, LGC
27	2013/35/EU Directive	<p>minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)/Development of the regulation regarding the metrology needs for the environment monitoring (radioactivity and dosimetry monitoring).</p> <p>Development and implementation of regulations regarding the metrology for the medical appliances of the ionising radiation (radiodiagnostic – mainly for CT investigations, radiotherapy mainly for LINAC use and radiosurgery).</p> <p>Council may, by means of directives, adopt minimum requirements for the encouragement of improvements, in particular of the working environment, to guarantee a better level of protection of the health and safety of workers. Such directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.</p>	PTB, NPL, INRIM, RISE, STUK (Radiation and Nuclear Safety Authority Finland), LNE, VSL (based on ICNIRP recommendations) IFIN-HH
28	94/62/EC New Approach Directive	Packaging and packagingwaste/ Whereas the differing national measures concerning the management of packaging and packaging waste should be harmonized in order, on the one hand, to prevent any impact thereof on the environment or to reduce such impact, thus providing a high level of environmental protection, and, on the other hand, to ensure the functioning of the- internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community;	LGC, INRIM, BVL, RISE

29	1223/2009/EC New Approach Regulation	<p>Cosmetic products/</p> <p>This Regulation aims at simplifying procedures and streamlining terminology, thereby reducing administrative burden and ambiguities. Moreover, it strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health.</p>	LGC, PTB, BAM, RISE
30	1935/2004/EC Regulation	<p>Materials and articles intended to come into contact with food/</p> <p>The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.</p>	LGC, INRIM, BAM, BVL, RISE
31	2014/40/EU Directive	<p>Tobacco products/</p> <p>The approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC</p>	LGC, RISE
32	2009/48/EC NLF (New Approach) Directive	<p>Toy safety/</p> <p>Approximation of the laws of the Member States concerning the safety of toys (3) was adopted in the context of establishing the internal market in order to harmonise the safety levels of toys throughout the Member States and to remove obstacles to trade in toys between Member States.</p>	LGC, RISE

33	2011/696/EU Recommendation	<p>EU recommendation of nanomaterial for regulatory purpose/</p> <p>The definition in this Recommendation should be used as a reference for determining whether a material should be considered as a ‘nanomaterial’ for legislative and policy purposes in the Union. The definition of the term ‘nanomaterial’ in Union legislation should be based solely on the size of the constituent particles of a material, without regard to hazard or risk. This definition, based only on the size of a material, covers natural, incidental or manufactured materials.</p>	LGC, INRIM, RISE
34	1169/2011/EU Regulation	Food Information for Consumers Regulation – need for metrological methods for nanomaterials and allergens in food	LGC, RISE
35	2015/2283/EU (Novel Food) Regulation	Intended for the characterisation of manufactured nanomaterials in food	LGC, INRIM, RISE
36	10/2011/EU Regulation	<p>Plastic materials and articles intended to come into contact with food. It makes specific reference to nanomaterials in plastic FCM.</p> <p>Commission Recommendation (EU) 2017/84 of 16 January 2017 advised on the monitoring of mineral oil hydrocarbons (considered mutagenic and carcinogenic) in food and in materials and articles intended to come into contact with food.</p>	LGC, INRIM, PTB, BAM, UBA, RISE

37	Regulation (EU) 2017/745 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	Many medical devices contain or are coated with nanomaterials	LGC, INRIM
38	1999/519/EC Recommendation	The limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz).	PTB, INRIM, RISE
39	2006/25/EC Directive	<p>Minimum health and safety requirements regarding the exposure with artificial optical radiation (down to 300 GHz)/</p> <p>Minimum requirements for encouraging improvements, especially in the working environment, to guarantee a better level of protection of the health and safety of workers. Such directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized enterprises (SMEs).</p>	PTB, RISE
40	2014/35/EU NLF (New approach) Directive	<p>Low Voltage (LVD)/</p> <p>harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast)</p>	NMIs offering photobiological testing of lamps and luminaires (METAS, NPL,...)
41	Directive 80/181/EEC (repealing Directive 71/354/EEC)	<p>Units of measurements/</p> <p>The approximation of the laws of the Member States relating to units of measurement</p>	(Proposed by MIRS)
42	Nanomaterials	see Rauscher et al., “Regulatory Aspects of Nanomaterials in the EU”, Chem. Ing. Tech. 2017, 89, No. 3, 224–231	RISE, NIMs involved in Nanometrology

43	305/2011/EU Regulation NLF	Construction products The rules of Member States require that construction works be designed and executed so as not to endanger the safety of persons, domestic animals or property nor damage the environment	MIKES VTT, NSAI, LNE, NPL,RISE, FORCE, BAM, SIQ, ZAG
44	2013/29/EU Directive NLF	Pyrotechnic Articles The free movement of pyrotechnic articles within the internal market while ensuring a high level of protection of human health and safety and the protection of consumers and professional end-users.	BAM
45	2013/53/EU Directive NLF	Recreational craft and personal watercraft	MIKES VTT
46	2014/28/EU Directive NLF	Civil Explosives 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)	BAM
47	2014/29/EU Directive NLF	Simple Pressure Vessels The harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels	FORCE, RISE
48	2014/33/EU Directive NLF	Lifts The harmonisation of the laws of the Member States relating to lifts and safety components for lifts	There are no NMI or DI in NANDO database.

49	2014/90/EU Directive NLF	Marine Equipment	FORCE
50	2016/424/EU Regulation NLF	Cableway installation Cableway installations are mainly lift systems, such as funicular railways, aerial ropeways (cable cars, gondolas, chairlifts) and drag lifts. Traction by cable and the passenger transport function are the essential criteria in determining whether a cableway installation is covered by this Regulation.	There are no NMI or DI in NANDO database.
51	Directive 2010/75/EU	the Industrial Emissions Directive or IED	
52	Directive 2008/50/EC	Air Quality Directive (Ambient air quality and cleaner air for Europe)	NPL, VSL
53	Directive 2000/14/EC	Outdoor Noise directive - Noise Emission by Outdoor Equipment	
54	Commission Regulation (EC) No 37/2005 of 12 January 2005	Monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption Text with EEA relevance	
55	2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network		NMIs onsite testing of lighting installations (INRIM,METAS,...)
56	2010/31/EU	Energy performance of buildings	VSL

57	2009/28/EC promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC	Use of energy of renewable sources	
58	Directive 2004/107/EC	Arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air	NPL, VSL, +...
59	NLF Regulation 765/2008	REGULATION (EC) No 765/2008 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out requirements for accreditation and market surveillance relating to marketing of products and repealing Regulation (EEC) No 339/93	LNE, NPL, RISE, ...
60	2004/40/EC Physical Agents Directive		
61	2001/83/EC Directive on medicinal products for human use		
62	2002/98/EC Directive on processing, storage and distribution of human blood and blood components		
63	2002/49/EC Directive on the assessment and management of environmental noise	Assessment and management of environmental noise	PTB

64	2003/10/EC Directive on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)	Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)	PTB
65	2006/66/EC Bateries Directive		
66	2008/98/EC Waste Directive		
67	2003/55/EC Directive concerning common rules for the internal market in natural gas		
68	2012/33/EU (amendment on Directive 1999/32/EC) Sulphur Directive		
69	2007/2/EC INSPIRE Directive		
70	2010/75/EU Industrial Emissions Directive (IED)		
71	2001/81/EC Directive on national emission ceilings for certain atmospheric pollutants (NEC) 2001/81/EC		
72	2002/95/EC Hazardous Substances RoHS) in Electrical and Electronic Equipment Directive		

73	EU MARINE STRATEGY FRAMEWORK DIRECTIVE Directive 2008/56/EC, June 2008. Off. J. Eur. Union, vol. L164, pp. 19-40, 2008 European Commission, 2010, "Commission Decision 2010-09-01 on Criteria and Methodological Standards on Good Environmental Status of Marine Waters. (2010/477/eu)	EU MSFD Mandates member states to achieve Good Environmental Status for oceans - includes UNDERWATER ACOUSTIC NOISE as a pollutant that must be monitored	NPL, DFM, TUBITAK
74	EU Habitats' Directive 92/43/EC, and from EC Directive 2001/42/EC govern the protection of the marine environment in Europe	Habitats Directive Includes provision for protection of marine species (mammals) from underwater noise pollution in ocean	NPL, DFM, TUBITAK
75	European regulation 2002/44 CE	Vibration and human exposure	PTB, LNE, INRIM, GUM
76	European regulation 1993 93/42EEC MEDICAL DEVICES DIRECTIVE	Human exposure to medical ultrasound	NPL, PTB, INRIM
77	Council Directive 71/347/EEC (old directive, new standards)	Measuring of the standard mass per storage volume of grain (mass per hectolitre of cereals)	BRML(INM) + ...

1 Responsibility derives from explicit legal assignment, notification under European Directive or national research priority of NMIs (? Wording)2 Measuring instruments may only be placed on the market if they fulfill the requirements of the measuring instrument regulation (Messmittelverordnung/MessMV, SR 941.210) as well as of the measuring instrument-specific regulations. MessMV stipulates the general requirements of the MID, the measuring instrument-specific regulations reflect the Annexes of the MID.

TABLE 2.

	Reference	Name of Regulation/ General topic	NMI/DI ¹ Interest	Additional information on standards/ normative documents	Why is measurement needed to support these regulations?	NMI responsibility/ formal or other broad responsibility	Possible activities within EURAMET TC or Task Group	What Research is needed to underpin this regulation?	Comments
1	2014/30/EU NLF (New Approach) Directive	Electromagnetic compatibility (EMC) (recast) / The harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)	LNE, RISE, LNMIC, PTB FORCE Certification A/S LABORATORIO CENTRAL OFICIAL DE ELECTROTECNIA (LCOE) INTA - Instituto Nacional de Tecnologia Aeroespacial	https://ec.europa.eu/growth/sing-le-market/european-standards/harmonised-standards/electromagnetic-compatibility_en		(37), (45), Article 24- very important, Article 32, Article 34	TC-EM TC-F (EMPIR JRP-i13) TC-L TC-M TC-Q	yes	IND60 EMC ENG03 LNG ENG60 LNG II CK: there is a proposal by WELMEC wg13 to retract EN 14154 and publish EN ISO 4064
2	2014/34/EU NLF (New Approach) Directive	Equipment for explosive atmospheres (ATEX) / The harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)	PTB, RISE, VTT Bundesanstalt für Materialforschung und -prüfung (BAM) SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ	https://ec.europa.eu/growth/sing-le-market/european-standards/harmonised-standards/equipment-explosive-atmosphere_en		(26)-, Chapter 3, Article 21- very important, Article 29- very important, Annex II-IX		yes	
3	2009/125/EC New Approach Directive	Ecodesign and energy labelling/ Establishing a framework for the setting of ecodesign requirements for energy-related products (recast)	PTB, INRIM, VSL	http://ec.europa.eu/growth/sing-le-market/european-standards/harmonised-standards/ecodesign_en		Article 8	TC-EM	yes	ENG02 Harvesting ENG05 Lighting ENG62 MESaL IND04 MetroMetal

4	2012/27/EU Directive EED	<p>Energy efficiency/ The Union is facing unprecedented challenges resulting from increased dependence on energy imports and scarce energy resources, and the need to limit climate change and to overcome the economic crisis. Energy efficiency is a valuable means to address these challenges. It improves the Union's security of supply by reducing primary energy consumption and decreasing energy imports. It helps to reduce greenhouse gas emissions in a cost-effective way and thereby to mitigate climate change. Shifting to a more energy-efficient economy should also accelerate the spread of innovative technological solutions and improve the competitiveness of industry in the Union, boosting economic growth and creating high quality jobs in several sectors related to energy efficiency.</p>	PTB, INRIM, RISE, VSL			There are no informations about conformity assessment procedure, conformity or notified bodies.	TC-EM	yes	ENG02 Harvesting ENG05 Lighting ENG62 MESaIL IND04 MetroMetal

5	<p>2013/59/Euratom Directive</p> <p>- StrVG – Strahlenschutzvorsorgegesetz - Richtlinie zur Kontrolle der Eigenüberwachung radioaktiver Emissionen aus Kernkraftwerken - REI – Richtlinie zur Emissions- und Immissionsüberwachung kerntechnischer Anlagen - StrlSchV – Strahlenschutzverordnung - RöV – Röntgenverordnung - Qualitätssicherungsrichtlinie für die Röntgendiagnostik - Sachverständigen-Richtlinie Uusi säteilylaki (1.1.2018)</p> <p>Verordnung des EJPD vom 7. Dezember 2012 über Messmittel für ionisierende Strahlung (StMmV, SR 941.210.5)</p>	<p>Basic Safety Standard/ Laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom</p>	<p>PTB, BAM, VTT, STUK (Radiation and Nuclear Safety Authority Finland), METAS, VSL</p>	<p>https://www.ncbi.nlm.nih.gov/pubmed/24729590</p>		<p>There are no informations about conformity assessment procedure, conformity or notified bodies.</p>	<p>TC-PR</p>	<p>yes</p> <p>Missing measuring instruments which can provide necessary traceability</p>	<p>Added are the national regulation which relay on Basic Safty Standards Directive</p> <p>ENV09 MetroRWM</p> <p>ENV54 MetroDecom</p> <p>ENV57 MetroERM HLT09 MetrExtRT HLT11 MetroMRT IND04 MetroMetal</p>
6	<p>2000/60/EC Directive</p>	<p>Water Directive (framework for Community action in the field of water policy)/ Establishing a framework for Community action in the field of water policy</p>	<p>PTB, BAM, INRIM, RISE, LGC</p>	<p>http://ec.europa.eu/environment/water/water-framework/index_en.html</p>		<p>There are no informations about conformity assessment procedure, conformity or notified bodies. But some other informations could be useful: ANNEX I- INFORMATION REQUIRED FOR THE LIST OF COMPETENT AUTHORITIES</p>	<p>TC-MC</p>	<p>yes</p> <p>Necessery infrastructure is still not developed (no reference laboratorie at EU level)</p>	<p>ENV08 WFD ENV05 Ocean ENV51 MeTra</p>

7	2013/51/Euratom Directive	Directive on protection against radioactive substances in drinking water/ Establishing a framework for Community action in the field of water policy.	PTB, RISE			There are no informations about conformity assessment procedure, conformity or notified bodies, but some other informations could be useful: Article 6- paragr. 3.- laboratory measurment Annex II- paragr.1.	TC-IR	yes	
8	2017/745/EU (repealing 93/42/EEC) New Approach Regulation 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	Medical devices (MD) / This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other.	NSAI, RISE, VSL, LNE (G-MED), VTT, INRIM SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - (SIQ), TÜBİTAK UME Medical Metrology Laboratory	https://ec.europa.eu/growth/sin-gle-market/european-standards/harmonised-standards/medical-devices_en	Traceability for medical devices and measurements are missing due to multidisciplinary nature of devices.	(56), (60), (61), Article	TC-F TC-T TC-TF TC-M TC-IR TC-EM TC-MC TGH-Task Group Health	R&D on multiparametric (i.e., pressure, flow, temperature, electrical..) measurement and calibration systems.	This directive could be an opportunity for a coordinated structure under EURAMET (comment JörnStenger)/ comment TC-IR: The well-established quality assurance system for the use of therapy and diagnostic doseimeters (dosimetry for therapy and diagnostic radiology) in routine will directly effect by this new medical device regulation. HLT03 DUTy IND56 Q-AIMDS 17IND01

9	<p>Regulation 2017/745 (repealing Directive 90/385/EEC on Active Implantable Medical Devices)</p> <p>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</p>	<p>Medical devices: activeimplantable/</p> <p>The approximation of the laws of the Member States relating to active implantable medical devices</p>	<p>NSAI, LNE (G-MED) INRIM</p>	<p>http://ec.europa.eu/growth/sing-le-market/european-standards/harmonised-standards/implantable-medical-devices/</p>		<p>Very important M4-Paragraph 10. M1-Paragraph 5.</p>	<p>TC-EM</p>		
10	<p>2017/746/EU (repealing 98/79/EC) New Approach Regulation</p>	<p>In.vitro diagnostic (IVD)/</p> <p>This Regulation aims to ensure the smooth functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for in vitro diagnostic medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other.</p>	<p>PTB, NSAI, LNE (G-MED), VTT, INRIM, LGC</p>	<p>http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0746</p> <p>https://ec.europa.eu/growth/sing-le-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en</p>		<p>(51), Chapter V-very important, Article 49- very important, Annex X, Annex XI</p>	<p>TC-MC TC-EM</p>		<p>HLT04 Biosurf HLT05 Metallomics HLT08 INFECT-MET SIB54 Bio-SITrace 15HLT01 15HLT02</p>

11	2014/65/EU Directive	Markets in Financial Instruments Directive (MiFID II)/ The purpose of this Directive is to cover undertakings the regular occupation or business of which is to provide investment services and/or perform investment activities on a professional basis. Its scope should therefore not cover any person with a different professional activity.	VSL, NMIs whose data are evaluated by BIPM for contributions to International Atomic Time	https://ec.europa.eu/info/business-economy-euro/banking-and-finance/financial-markets/securities-markets/investment-services-and-regulated-markets-markets-financial-instruments-directive-mifid_en		The term "conformity assessment" is not mentioned.	TC-TF		
12	NLF Regulation 765/2008	REGULATION (EC) No 765/2008 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out requirements for accreditation and market surveillance relating to marketing of products and repealing Regulation (EEC) No 339/93	LNE, NPL, RISE, VSL...	ISO/IEC, Draft International Standard ISO/IEC DIS 17025 : General requirements for the competence of testing and calibration laboratories, 2017	Use of measurement uncertainty in conformity assessment		TC-IM + MATHMET		EMPIR 2018 SIP-NEW04 CASoft, UNECE working group on market surveillance/17SIP05

13	2013/35/EU Directive	<p>minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)/Development and implementation of regulations regarding the metrology for the medical appliances of the ionising radiation (radiodiagnostic – mainly for CT investigations, radiotherapy mainly for LINAC use and radiosurgery).</p> <p>Council may, by means of directives, adopt minimum requirements for the encouragement of improvements, in particular of the working environment, to guarantee a better level of protection of the health and safety of workers. Such directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.</p>	PTB, NPL, INRIM, RISE, STUK (Radiation and Nuclear Safety Authority Finland), LNE, VSL (based on ICNIRP recommendations), IFI N-HH	https://osha.europa.eu/fr/legislation/directives/directive-2013-35-eu-electromagnetic-fields		<p>There are no informations about conformity assessment procedure, conformity or notified bodies.</p> <p>Chapter II (Article 4, 6) Chapter IV (Article 14) Annexes</p>	TC-EM	yes	
14	2014/94/EU Directive	Deployment of alternative fuels infrastructure	PTB, VSL	https://www.cenelec.eu/about-cenelec/what-stand-for-support-legislation/european-mandates.html		<p>There are no informations about conformity assessment procedure, conformity or notified bodies.</p>		yes	
15	89/686/EEC New Approach Directive Regulation 2016/425 applicable as of 21 April 2018	Personal protective equipment (PPE)/ The approximation of the laws of the Member States relating to personal protective equipment	LNE-IRSN	https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment_en					

30	2004/40/EC Physical Agents Directive								HLT06 MRI Safety
31	2002/49/EC Directive on the assessment and management of environmental noise	Assessment and management of environmental noise	PTB		Traceability for the acoustic measurement necessary, managing of type approvals following national laws	TC-AUV NMIs responsible for traceability and type approvals	research projects and comparisons	New methods required to include new frequency ranges and new applications, introduce traceability for sensor networks for environmental noise mapping	HL01 Ears 15HLT03
32	2003/10/EC Directive on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)	Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)	PTB		Traceability for the acoustic measurement necessary, managing of type approvals following national laws	TC-AUV NMIs responsible for traceability and type approvals	research projects and comparisons	new methods for ultrasound and infrasound at work places	HL01 Ears 15HLT03
33	305/2011/EU Regulation NLF	Construction products The rules of Member States require that construction works be designed and executed so as not to endanger the safety of persons, domestic animals or property nor damage the environment	MIKES VTT, NSAI, LNE, NPL, RISE, FORCE, BAM, SIQ, ZAG,	https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/construction-products_fr		Annex V, Article 2. Article 46 Paragraph 2.a,	TC-IM		SIB52 Thermo
34	EU MARINE STRATEGY FRAMEWORK DIRECTIVE Directive 2008/56/EC, June 2008. Off. J. Eur. Union, vol. L164, pp. 19-40, 2008 European Commission, 2010, "Commission Decision 2010-09-01 on Criteria and Methodological Standards on Good Environmental Status of Marine Waters. (2010/477/eu)	EU MSFD Mandates member states to achieve Good Environmental Status for oceans - includes UNDERWATER ACOUSTIC NOISE as a pollutant that must be monitored	NPL, DFM, TUBITAK,	http://publications.jrc.ec.europa.eu/repository/handle/11111111/30979 http://publications.jrc.ec.europa.eu/repository/handle/11111111/30973	Traceability for the acoustic measurement necessary, development of improved in-situ measurement methods	TC-AUV NMIs responsible for traceability and R&D on methods	research projects and comparisons	New methodologies required for in-situ measurement of noise sources (ships, impulsive sounds...). New standard methodologies for calibration of new autonomous digital instruments. New methods for measurement of ambient ocean noise. Standards for particle motion detection	

35	EU Habitats' Directive 92/43/EC, and from EC Directive 2001/42/EC govern the protection of the marine environment in Europe	Habitats Directive Includes provision for protection of marine species (mammals) from underwater noise pollution in ocean	NPL, DFM, TUBITAK,		Traceability for the acoustic measurement necessary, development of improved in-situ measurement methods	TC-AUV NMIs responsible for traceability	research projects and comparisons	New methodologies required for in-situ measurement of noise sources (ships, impulsive sounds...). New standard methodologies for calibration of new autonomous digital instruments. New methods for exposure assessment. Standards for particle motion detection	
36	European regulation 2002/44 CE	Vibration and human exposure	PTB, LNE, INRIM, GUM,		Traceability for the acoustic measurement necessary, managing of type approvals following national laws	TC-AUV NMIs responsible for traceability and R&D on methods	research projects and comparisons	new methods for high and low frequencies. Seismic and tsunami detection and warning	
37	European regulation 1993 93/42EEC MEDICAL DEVICES DIRECTIVE	Human exposure to medical ultrasound	NPL, PTB, INRIM		Traceability for the acoustic measurements and for ultrasound output and exposure assessment	TC-AUV NMIs responsible for traceability and R&D on methods	research projects and comparisons	Exposure assessment for therapeutic ultrasound (eg HITU), quantitative imaging for diagnostic	
38	2010/31/EU	Energy performance of buildings		Evacuation Lighting in Road Tunnels			TC-PR	To quantify the energy performance of buildings radiative energy transfer plays an important role. Material properties like transmission, reflection, emissivity need to be measured more accurately here than is currently possible. There also is a need for reference standards, especially for the providing to (portable) instruments for production of onsite measurements.	

39	Council Directive 71/347/EEC (old directive, new standards)	Measuring of the standard mass per storage volume of grain (mass per hectolitre of cereals)	BRML(INM) + ...		A better understanding of the needs of the agricultural sector for measuring the mass per hectolitre of cereals and of other agricultural products. Cooperation with manufacturers of electronic or mechanical instruments that measure the mass per hectolitre of agricultural products. Traceability for these measurements to ensure stability, comparability and coherence across Europe.	Listed as an example in EN ISO 7971-2		New methods required to reduce uncertainty, include new instruments and other agricultural products, improve comparability and consistency across Europe.	
40	10/2011/EU Regulation	Plastic materials and articles intended to come into contact with food. It makes specific reference to nanomaterials in plastic FCM. Commission Recommendation (EU) 2017/84 of 16 January 2017 advised on the monitoring of mineral oil hydrocarbons (considered mutagenic and carcinogenic) in food and in materials and articles intended to come into contact with food.	LGC, INRIM, PTB, RISE, BAM, UBA	https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en		CHAPTER 2, 3	TC-MC	Lack of definition in the legal text – reliance on the Commission Recommendation/Definition; Risk Assessment Methodologies and Guidance (EFSA guidance being developed); Analytical tools (needed) for Risk Assessment and Enforcement; Identification and characterisation method development and validation; Methods to measure specific migration of nanomaterials from FCM to appropriate foods / food simulants; Reference materials and Reference/appropriate FCM matrices; Laboratory capacity for enforcement	
41	Directive 2000/14/EC	Outdoor Noise directive - Noise Emission by Outdoor Equipment		http://ec.europa.eu/environment/noise/directive_en.htm			TC-AUV	New methods required to reduce uncertainty, improve comparability and address the possibility of reduced limit values in future and also emerging pollutants	