

Strategy of Montenegro

Implementation of the Acquis in the Field of Free Movement of Goods 2014-2018

Indicative Five-year Action plan

Updated on May 2016

STRATEGIC FRAMEWORK			
Legal Act	Status	Competent Institution/ Implementation body	Adoption Period
HORIZONTAL MEASURES			
Action plan for compliance with Articles 34-36 TFEU	Realized – Adopted at the MNE Government session on 17.12.2015	Ministry of Economy Competent ministries ¹	IV Q 2015
Strategy for Accreditation Development 2015 - 2018	Realized – Adopted at the MNE Government session on 20.11.2014	MoE Accreditation Body of Montenegro	IV Q 2014
Action plan for implementation of the Strategy for Accreditation Development / Annual	AP 2015: Adopted at the MNE Government session on 20.11.2014 AP 2016: Adopted at the MNE Government session on 11.02.2016	MoE Accreditation Body of Montenegro	IV Q 2016 (AP 2017) IV Q 2017 (AP 2018)
Strategy of Development of Standardization in Montenegro 2015 - 2018	Realized – Adopted at the MNE Government session on 20.11.2014	MoE Institute of Standardization	IV Q 2014
Action plan for Development of Standardization 2015-2018.	(AP 2015) Realized – Adopted at the MNE Government session on 20.11.2014 AP 2016: Adopted at the MNE Government session on 11.02.2016	MoE Institute of Standardization	IV Q 2016 (AP 2017) IV Q 2017 (AP 2018)
Strategy of Metrology Development in	Realized – Adopted at the MNE Government	MoE	IV Q 2015

¹ Ministries which are in charge of preparation, adoption and implementation of regulations for different types of products

Montenegro for period 2016 - 2018	session on 28.12.2015	Bureau of Metrology	
National Strategy for Market Surveillance 2017 – 2020		- MoE - Administration for Inspection Affairs - Other market surveillance authorities	IV Q 2017
General Programme of Market Surveillance / Annual	NP 2015 Realized - Coordinating Body for Market Surveillance adopted a general Programme of Market Surveillance for 2015 NP 2016 Realized - Coordinating Body for Market Surveillance adopted a general Programme of Market Surveillance for 2016	- Coordinating Body for Market Surveillance - Administration for Inspection Affairs - Other market surveillance authorities	continuously

OLD APPROACH STRATEGIES

National Strategy of Chemicals Management	Realized – Adopted at the MNE Government session on 15.01.2015.	Ministry of Sustainable Development and Tourism (Environmental Protection Agency)	I Q 2015
Action plan for National Strategy of Chemicals Management 2015-2018	Realized – Adopted at the MNE Government session on 15.01.2015.	Ministry of Sustainable Development and Tourism (Environmental Protection Agency)	I Q 2015

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
HORIZONTAL MEASURES METROLOGY, STANDARDIZATION, ACCREDITATION AND MARKET SURVEILLANCE			
Regulation (EC) 765/2008	Law on Amendments to Law on Accreditation (OG of MNE 43/15) (MoE)	N/A – primary law	
Regulation (EC) 765/2008	Law on Surveillance of Products on Market (OG of MNE 33/14) (MoE)	N/A – primary law	
	Law on amendments of Law on Surveillance of Products on Market (MoE)	N/A – primary law	II Q 2018
Regulation (EC) 764/2008	Law on Surveillance of Products on Market (OG of MNE 33/14) (MoE)	N/A – primary law	

Directive 2001/95/EC	Law on Surveillance of Products on Market (OG of MNE 33/14) (MoE)	N/A – primary law	
Directive 87/357/EEC	Law on General Product Safety (OG of MNE 45/14) (MoE)		
	Law on amendments of Law on General Product Safety (MoE)	N/A – primary law	III Q 2016
Regulation (EU) 1025/2012	Law on Standardization (MoE)	N/A – primary law	IV Q 2016
Decision 768/2008/EC	Law on Technical Requirements for product and Conformity Assessment (MoE)	N/A – primary law	II Q 2017
Directive 80/181/EEC Directive 2009/3/EC	Decree of legal units of measurement (OG of MNE 22/09 and 72/15) (MoE)	Law on Metrology	IV Q 2015
Directive 2009/34/EC	Rulebook on common provisions for measuring instruments and methods of metrological control (MoE)	Law on Metrology	IV Q 2018
Directive 76/211/EEC Directive 2007/45/EC	Rulebook on amendments of Rulebook on pre-packed products	Law on Metrology	II Q 2017

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
NEW APPROACH INDIVIDUAL PRODUCT GROUP DIRECTIVES			
Directive 2004/108/EC	Rulebook on electromagnetic compatibility (OG MNE 50/14) (MoE)	Law on Technical Requirements for Products and Conformity Assessment (LTRPCA)	
Directive 2014/30/EU	Rulebook on electromagnetic compatibility (MoE)	LTRPCA	II Q 2017

Directive 2014/29/EU	Rulebook on simple pressure vessels (MoE)	LTRPCA	II Q 2017
Directive 2014/35/EU	Rulebook on low voltage electrical equipment (MoE)	LTRPCA	II Q 2017
Directive 2014/33/EU	Rulebook on safety of lifts (MoE)	LTRPCA	II Q 2017
Directive 2014/68/EU	Rulebook on pressure equipment (MoE)	LTRPCA	II Q 2017
Directive 2009/142/EC	Rulebook on gas appliances (OG MNE 10/15) (MoE)	LTRPCA	
Regulation EU 2016/426	Rulebook on appliances burning gaseous fuels (MoE)	LTRPCA	IV Q 2017
Directive 92/42/EC	Rulebook on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OG MNE 41/15) ² (MoE)	LTRPCA	
Directive 75/324/EEC	Rulebook on Aerosol Dispensers (OG MNE 10/15) (MoE)	LTRPCA	
	Amendments of the Rulebook on Aerosol Dispensers (MoE)	LTRPCA	I Q 2017
Directive 2009/127/EC	Rulebook on amendments to Rulebook on safety of machinery (MoE)	LTRPCA	II Q 2017
Directive 2014/34/EU	Rulebook on equipment and protective systems intended for use in potentially explosive atmospheres (MoE)	LTRPCA	IV Q 2018
Directive 1999/5/EC	Rulebook on requirements for RTT equipment (OG MNE 46/14) (MoIST)	Law on Electronic Communications LTRPCA	
Directive 2014/53/EU	Rulebook on requirements for Radio Equipment (MoIST)	Law on Electronic Communications LTRPCA	II Q 2017
Directive 2014/32/EU Directive 2015/13/EU	Rulebook on measuring Instruments – MID (MoE)	Law on metrology LTRPCA	II Q 2017
Directive 2014/31/EU	Rulebook on non-automatic weighing Instruments (MoE) – NAWI (MoE)	Law on metrology LTRPCA	II Q 2017

² Relevant acquis and adoption period is mentioned in the section for ECO DESIGN

Directive 89/686/EEC	Rulebook on Personal Protective Equipment (OG MNE 17/15) (MoE)	LTRPCA	
NEW APPROACH CABLEWAY			
Directive 2009/9/EC	Rulebook on conditions for cableways installations designed to carry persons (OG MNE 42/14) (MoTMA)	Law on Safety, Organization and Efficiency of Rail Transport	
Regulation EU 2016/424	Rulebook on conditions for cableways installations designed to carry persons (MoTMA)	Law on Safety, Organization and Efficiency of Rail Transport	I Q 2018
NEW APPROACH ECO-DESIGN			
Directive 2009/125/EC (Framework directive)	Law on Efficient Use of Energy (OG MNE 57/2014 & 3/2015) (MoE)	N/A – primary law	
	Rulebook on ecodesign of energy related products (OG MNE 9/2016) (ME)	LEUE LTRPCA	
Regulation (EC) 2009/245	Rulebook on ecodesign requirements for non-directional household lamps(ME)	LEUE LTRPCA	IV Q 2016
Regulation (EC) 2009/244	Rulebook on ecodesign requirements for fluorescent lamps without integrated ballast, high intensity discharge lamps, and ballasts and luminaires able to operate such lamps(ME)	LEUE LTRPCA	IV Q 2016
Regulation (EC) 2009/640	Rulebook on ecodesign requirements for electric motors(ME)	LEUE LTRPCA	IV Q 2016
Regulation (EC) 2013/813 Regulation (EC) 2013/814	Rulebook on ecodesign requirements for space and water heaters(ME)	LEUE LTRPCA	II Q 2018
Regulation (EC) 2008/1275	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EC) 2009/107	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017

Regulation (EC) 2009/278	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EC) 2009/642	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EC) 2009/643	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EU) 2012/1194	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EU) 2010/1015	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
NEW APPROACH MEDICAL DEVICES			
Regulation (EU) 2011/327	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE N/A – primary law	III Q 2017
Directive 93/42/EEC	Rulebook on classification and entry into register of Medical Devices (MoH)	LTRPCA Law on Medical Devices (LMD)	IV Q 2017 II Q 2018
Regulation (EU) 2012/206	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EU) 2012/547	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EC) 2009/641	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017
Regulation (EU) 2012/932	Rulebook amending the Rulebook on the setting of ecodesign requirements for products having an impact on energy consumption (ME)	LEUE LTRPCA	IV Q 2017

	Rulebook on vigilance and monitoring of medical devices on the market (MoH)	LMD	II Q 2018
	Rules on advertising of medical devices (MoH)	LMD	IV Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018
	Rulebooks on clinical trials of medical devices (MoH)	LMD	IV Q 2018
Directive 90/385/EEC	Law on Medical Devices (MoH)	N/A – primary law	III Q 2017
	Rulebook on classification and entry into register of medical devices (MoH)	LMD	II Q 2018
	Rulebook on vigilance and monitoring of medical devices on the market (MoH)	LMD	II Q 2018
	Rules on advertising of medical devices (MoH)	LMD	IV Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018
	Rulebooks on clinical trials of medical devices (MoH)	LMD	IV Q 2018
Directive 98/79/EEC	Law on Medical Devices (MoH)	N/A – primary law	III Q 2017
	Rulebook on classification and entry into register of medical devices (MoH)	LMD	II Q 2018
	Rulebook on vigilance and monitoring of medical devices on the market (MoH)	LMD	II Q 2018
	Rules on advertising of medical devices (MoH)	LMD	IV Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018
	Rulebooks on clinical trials of medical devices (MoH)	LMD	IV Q 2018
Directive 2003/12/EC	Law on Medical Devices (MoH)	N/A – primary law	III Q 2017
	Rulebook on classification and entry into register of medical devices (MoH)	LMD	II Q 2018
	Rulebook on vigilance and monitoring of medical devices on the market (MoH)	LMD	II Q 2018
	Rules on advertising of medical devices (MoH)	LMD	IV Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018
	Rulebooks on clinical trials of medical devices (MoH)	LMD	IV Q 2018
Directive 2003/32/EC	Law on Medical Devices (MoH)	N/A – primary law	III Q 2017
	Rulebook on classification and entry into register of medical devices (MoH)	LMD	II Q 2018
	Rulebook on vigilance and monitoring of medical devices on the market (MoH)	LMD	II Q 2018
	Rules on advertising of medical devices (MoH)	LMD	IV Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018
	Rulebooks on clinical trials of medical devices (MoH)	LMD	IV Q 2018
Directive 2005/50/EC	Law on Medical Devices (MoH)	N/A – primary law	III Q 2017
	Rulebook on classification and entry into register of medical devices (MoH)	LMD	II Q 2018
	Rulebook on vigilance and monitoring of medical devices on the market (MoH)	LMD	II Q 2018
	Rules on advertising of medical devices (MoH)	LMD	IV Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018
	Rulebooks on clinical trials of medical devices (MoH)	LMD	IV Q 2018

Regulation (EC) 722/2012	Law on Medical Devices (MoH)	N/A – primary law	III Q 2017
	Rulebook on classification and entry into register of medical devices (MoH)	LMD	II Q 2018
	Rulebook on vigilance and monitoring of medical devices on the market (MoH)	LMD	II Q 2018
	Rules on advertising of medical devices (MoH)	LMD	IV Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018
	Rulebooks on clinical trials of medical devices (MoH)	LMD	IV Q 2018
Regulation EU 207/2012	Law on Medical Devices (MoH)	N/A – primary law	III Q 2017
	Rulebook on classification and entry into register of medical devices (MoH)	LMD	II Q 2018
	Rulebook on the labeling of medical devices (MoH)	LMD	III Q 2018

**NEW APPROACH
CONSTRUCTION PRODUCTS**

Regulation EU 305/2011	Law on Construction Products (OG MNE 18/2016) (LCP)	N/A – primary law	
	Rulebook on adopting assessment document and on keeping records of issued assessment documents (MoSDT)	LCP	IV Q 2016
Regulation EU 305/2011 Regulation (EU) 1062/2013	Rulebook on content and form of technical assessment documents, as well as content and method of keeping records of issued technical assessment documents (MoSDT)	LCP	IV Q 2016
Regulation EU 305/2011 Regulation (EU) 574/2014 Regulation (EU) 157/2014	Rulebook on detailed form and content of declaration of performance (OG MNE 46/14) (MoSDT)	LCP	
Regulation EU 305/2011	Rulebook on labelling of construction products (OG MNE 46/14) (MoSDT)	LCP	
Regulation EU 305/2011 Regulation (EU) 568/2014	Rulebook on content of systems of assessment (OG MNE 46/14) (MoSDT)	LCP	
Regulation (EU) 305/2011	Rulebook on detailed conditions for issuing and revocation of designation for assessment and verification of constancy of performance and content and method of keeping record of issued and revoked designations (MoSDT)	LCP	IV Q 2016
	Rulebook on detailed conditions for issuing and revocation of designation for issuing technical assessment and assessment document, as well as list of group of products (MoSDT)	LCP	IV Q 2016

Regulation (EU) 305/2011 Regulation (EU) 1291/2014 Regulation (EU) 1292/2014 Regulation (EU) 1293/2014	Rulebook on fire classification of construction products (MoSDT)	LCP	IV Q 2016
	Decree on recognition of foreign documents and conformity markings of construction products (MoSDT)	LCP	IV Q 2016
	Rulebooks on technical requirements for various groups of construction products	LCP Law on Spatial Development and on Construction Works	Continuously 2016-2018

**NEW APPROACH
EXPLOSIVES FOR CIVIL USE
PYROTECHNIC ARTICLES**

Directive 2007/23/EC	Rulebook on technical requirements and conformity assessment procedures for explosives, for civil use (OG of MNE, No. 45/15 & 68/15) (MoIA)	Law on Explosive Substances (MoIA)	
Directive 2014/28/EU	Rulebook on technical requirements and conformity assessment procedures for explosives, for civil use (MoIA)	Law on Explosive Substances (MoIA)	IV Q 2018

Directive 93/15/EC	Rulebook on safety requirements to be met by pyrotechnic articles (OG of MNE, No. 42/15 & 67/15) (MoIA)	Law on Explosive Substances Law (MoIA)	
Directive 2013/29/EC	Rulebook on safety requirements to be met by pyrotechnic articles (MoIA)	Law on Explosive Substances Law (MoIA)	IV Q 2018

**NEW APPROACH
RECREATIONAL CRAFT**

Directive 2013/53/EU	Rulebook on criteria for yachts certification (MoTMA)	Law on Yachts	IV Q 2016
	Rulebook on boats certification (MoTMA)	Law on Safety of Maritime Navigation	IV Q 2017

**OLD APPROACH
DRUG PRECURSORS**

**NEW APPROACH
TOYS**

Directive 2009/48/EC	Rulebook on safety of toys (OG MNE 4/15) (MoH)	LTRPCA	
	Amendments of the Rulebook on safety of toys (MoH)	LTRPCA	IV Q 2017
EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period

**OLD APPROACH
COSMETIC PRODUCTS**

Regulation (EC) 1223/2009	Law on Cosmetic Products (MoH)		II Q 2018
	Rulebook on technical requirements for cosmetic products (MoH)	Law on Cosmetic Products	IV Q 2018

Regulation (EC) 273/2004	Rulebook on content of approval for use of precursors, and content of application for approval for use of precursors (OG MNE 4/15) (MoH)	Law on Control of Production and Circulation of Substances Used in Manufacture of Narcotic Drugs and Psychotropic Substances (LCPCS)	
	Rulebook on content of request and form of license for import, export, transit and transport of precursors (OG MNE 4/15) (MoH)	LCPCS	
	Rulebook on the content of license and license application for production of precursors (OG MNE 6/15) (MoH)	LCPCS	
	Rulebook on form and content of reports of legal entities that perform import or export of precursors (OG MNE 12/15) (MoH)	LCPCS	
	Rulebook on data and content of reports on production and trade in precursors (OG MNE 16/15) (MoH)	LCPCS	
	Rulebook on form and content and manner of delivery of notification on export of precursors (OG MNE 4/15) (MoH)	LCPCS	
	Rulebook on form, content, method of use and maintenance of statement of end user of precursors (OG MNE 4/15) (MoH)	LCPCS	
	Rulebook on content of marketing authorization and content of application for marketing authorization for precursors (OG MNE 4/15) (MoH)	LCPCS	
	Rulebook on content and maintenance of register of legal entities performing production, marketing, import, export, transit and transport of precursors (OG of MNE No. 32/15) (MoH)	LCPCS	
	Rulebook on content and manner of maintenance of records of legal entities engaged in production and/or trade in precursors (OG of MNE No. 32/15) (MoH)	LCPCS	
Regulation (EC) 273/2004	Law on Amendments to Law on Control of Production and Circulation of Substances Used in Manufacture of Narcotic Drugs and Psychotropic Substances (MoH)		IV Q 2018

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
OLD APPROACH MEDICINES³			
Directive 89/105/EEC	Law on Medicines (MoH)		I Q 2017
	Decree on criteria of setting maximum prices of medicines (OG of MNE No. 44/15 & 65/15) (MoH)	Law on Medicines (LM)	
	Decree on amendments of Decree on criteria of setting maximum prices of medicines (MoH)	Law on Medicines (LM)	I Q 2018
	Regulation on criteria for determining the basic and supplementary list of drugs(OG of MNE, No. 41/14)	Law on Health Insurance	
Directive 2001/82/EC	Law on Medicines (MoH)		I Q 2017
	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	

³ As far as the Regulation 470/2009 is concerned, Montenegro planned in original AP harmonization with this regulation before EU accession. However, in consultation with experts from EU IPA 2014 project, Montenegro was advised that it is not possible to align with this Regulation in pre-accession period as it regulates procedures for establishment of maximum level of residues of pharmacologically active substances in European Agency for medicines where only EU member states can participate. Accordingly, Montenegro is of the opinion, that in pre-accession period, Montenegro will continue with the implementation of »Rulebook on maximum level of quantity of residues of pharmacologically active substances in animal origin products« (published in "OG MNE", br.41/14) which is aligned with the Regulation 37/2010 (chapter 12) and which is at the same time related to the procedure of implementation of Regulation 470/2009 . Accordingly, Montenegro will prepare its institutions in pre-accession period for the implementation of this regulation and there is no national regulation in force that is in contradiction with this Regulation.

	Rulebook on wholesale of medicines (only for human medicines)(OG of MNE 72/15) (MoH)	LM	
	Rulebook on wholesale of veterinary medicines (MoARD)	LM	IV Q 2016
	Rulebook on labeling of medicines (only for human medicines) (OG of MNE 21/16) (MoH)	LM	
	Rulebook on labeling of veterinary medicines(MoARD)	LM	IV Q 2016
	Rulebook on mode of prescribing and dispensing of medicines (OG of MNE, No. 34/15) (only for human medicines) (MoH)	LM	
	Rulebook on mode of prescribing and dispensing of veterinary medicines (MoARD)	LM	IV Q 2016
	Law on medicines (MoH)		I Q 2017
	Rulebook on pharmacovigilance (OG of MNE 46/14) ⁴ (MoH)	LM	
Directive 2001/83/EC	Rulebook on the traditional herbal medicines (OG of MNE 4/15) ⁵ (MoH)	LM	
	Rulebook on homeopathic medicines (only for human medicines) (OG of MNE 6/15) ⁶ (MoH)	LM	
	Rulebook on homeopathic medicines (for veterinary medicines) (MoARD)		IV Q 2016
	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	

⁴ Provisions that are not harmonised in the current rulebook will be harmonised through the new Law on medicines and therefore we do not anticipate the need for the amendment of the Rulebook.

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	Rulebook on wholesale of medicines medicines (only for human medicines) (OG of MNE 72/15) (MoH)	LM	
	Rulebook on wholesale of veterinary medicines (MoARD)	LM	IV Q 2016
	Rulebook on labeling of medicines (only for human medicines) (OG of MNE 21/16) (MoH)	LM	
	Rulebook on labeling of veterinary medicines(MoARD)	LM	IV Q 2016
	Rulebook on mode of prescribing and dispensing of medicines (only for human medicines) (Gazette of MNE, No. 34/15) (MoH)	LM	
	Rulebook on mode of prescribing and dispensing of veterinary medicines (MoARD)	LM	IV Q 2016
Directive 2003/94/EC	Law on Medicines (MoH)		I Q 2017
	Guidelines on Good Manufacturing Practice (MoH)	LM	IV Q 2016
	Rulebook on manufacturers of medicines(OG of MNE, No 72/15) (MoH)	LM	
	Rulebook on traditional herbal medicines (OG of MNE, No 4/15) (MoH)	LM	
	Rulebook on homeopathic medicines (only for human medicines) (OG of MNE, No 6/15) (MoH)	LM	
	Rulebook on homeopathic medicines (for veterinary medicines) (MoARD)	LM	IV Q 2016
Directive 2005/28/EC	Law on Medicines (MoH)		I Q 2017
	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	

	Rulebook on advanced therapies (MoH)	LM	III Q 2017
	Rulebook on pharmacovigilance(OG of MNE 46/14) ⁷ (MoH)	LM	
Regulation (EC) 726/2004	Law on Medicines (MoH)		I Q 2017
Regulation (EC) 1950/2006	Law on Medicines (MoH)		I Q 2017
	Rulebook on advanced therapies (MoH)	LM	III Q 2017
Regulation (EC) 1235/2010	Rulebook on pharmacovigilance (OG of MNE 46/14) ⁸ (MoH)	LM	
Regulation (EC) 141/2000	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	
Regulation (EC) 847/2000	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	
Regulation (EC) 1901/2006	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	
	Rulebook on advanced therapies (MoH)	LM	III Q 2017
Regulation (EC) 1234/2008	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	
Directive 1991/412/EEC	Guidelines on Good Manufacturing Practice (MoH)	LM	IV Q 2016
	Rulebook on manufacturers of medicines (OG of MNE 72/15) (MoH)	LM	
Regulation (EC) 198/2013	Rulebook on labeling of medicines medicines (only for human medicines) (OG of MNE 21/16) (MoH)	LM	
	Rulebook on labeling of veterinary medicines(MoARD)	LM	IV Q 2016
Directive 2006/130/EC	Rulebook on mode of prescribing and dispensing of medicines (OG of MNE, No. 34/15) (only for human medicines) (MoH)	LM	

⁷ Provisions that are not harmonised in the current rulebook will be harmonised through the new Law on medicines and therefore we do not anticipate the need for the amendment of the Rulebook.

⁸ Provisions that are not harmonised in the current rulebook will be harmonised through the new Law on medicines and therefore we do not anticipate the need for the amendment of the Rulebook.

	Rulebook on mode of prescribing and dispensing of veterinary medicines (MoARD)	LM	IV Q 2016
	Rulebook on more detailed conditions for issuance, variations to and renewal of marketing authorization for a medicine (OG of MNE 21/16) (MoH)	LM	
Regulation (EU) 536/2014	Law on Medicines (MoH)		I Q 2017
Regulation (EU) 699/2014	Law on Medicines (MoH)		I Q 2017
Regulation (EU) 1252/2014	Law on Medicines (MoH)		I Q 2017
	Guidelines of good manufacturing process	LM	IV Q 2016

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
FERTILISERS			
Regulation (EC) 2003/2003	Law on Plant Nutrition (OG MNE 48/07 and 76/08) (MoARD)	N/A Primary Law	
	Rulebook on the types of fertilizers, the conditions for ammonium nitrate fertilizers of high nitrogen concentration, method of labeling and packaging of fertilizers (OGMN 32/15)	Law on Plant Nutrition	

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
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CHEMICALS⁹			
Regulation (EU) 689/2008	List of dangerous chemicals and products whose export is prohibited (OG MNE 31/14) (MoSDT)	Law on Chemicals	
	List of dangerous chemicals and products whose export is prohibited (MoSDT)	Law on Chemicals	IV Q 2018
	Rulebook on amendments of Rulebook on the procedure of prior notification and the procedure of issuing permits based on prior notification of export of chemicals (OG MNE 27/14) (MoSDT)	Law on Chemicals	
	Rulebook on amendments of Rulebook on the procedure of prior notification and the procedure of issuing permits based on prior notification of export of chemicals (MoSDT)	Law on Chemicals	IV Q 2018
Regulation (EU) 1272/2008 Regulation (EU) 1907/2006 Regulation (EU) 689/2008	Law Amending the Law on Chemicals		II Q 2016
Regulation (EU) 326/2015 Regulation (EU) 1494/2015 Regulation (EU) 628/2015 Regulation (EU) 317/2014 Regulation (EU) 474/2014 Regulation (EU) 1271/2013 Regulation (EU) 126/2013	Rulebook amending the Rulebook on prohibitions and restrictions on use, marketing and manufacturing of chemicals posing an unacceptable risk to human health and the environment (OG MNE 12/16)	Law on Chemicals	
Regulation (EU) 830/2015	Rulebook amending the Rulebook on the content of the safety data sheet for chemicals	Law on Chemicals	IV Q 2016
Regulation (EU) 282/2015	Rulebook amending the Rulebook on more detailed content of the dossier and register of chemicals	Law on Chemicals	III Q 2016
Regulation (EU) 900/2014	Rulebook amending the Rulebook on the methods of testing of hazardous properties of chemicals	Law on Chemicals	III Q 2017
Regulation (EU) 2014/1297	Rulebook amending the Rulebook on the manner of classification, packaging and labelling of chemicals and certain products in accordance with the UN Globally Harmonised System of Classification and Labelling of Chemicals	Law on Chemicals	IV Q 2017

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
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⁹ In addition to items listed below, alignment with the Regulation (EC) 850/2004 and Regulation (EC) 1102/2008 is related to chapter 27 and is not the subject of this Action Plan

OLD APPROACH BIOCIDES			
Regulation (EU) 528/2012	Law on Biocide Products (MoSDT)	N/A – primary law	IV Q 2016
	List of Active substances (MoSDT)	Law on Biocide Products	IV Q 2016
	Rulebook on types of biocide products depending on the method of use, organisms they affect, facilities in which they are used and surfaces treated with biocides (MoSDT)	Law on Biocide Products	IV Q 2016
	Rulebook on conditions for placing on the market and in use of a biocide and on the content of the authorization (MoSDT)	Law on Biocide Products	IV Q 2016
	Rulebook on more detailed content of a technical dossier and basic information on biocidal products (MoSDT)	Law on Biocide Products	IV Q 2016
	Rulebook on the methods of testing the efficacy of a biocidal product(MoSDT)	Law on Biocide Products	IV Q 2016
	Rulebook on the method of risk assessment on the basis of a technical dossier(MoSDT)	Law on Biocide Products	IV Q 2016
	Rulebook on the content and method of keeping the register of biocides(MoSDT)	Law on Biocide Products	IV Q 2016

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
OLD APPROACH MOTOR VEHICLES			
Directive 2007/46 (Framework directive) Regulation (EU) 1171/2014 Regulation (EU) 2015/166 Regulation (EU) 2015/45	Rulebook on approval of motor vehicles (MoTMA)	Law on Road Traffic Safety (LRTS) Law on Technical Requirements for Products and Conformity Assessment (LTRPCA)	IV Q 2016
Directive 70/157/EEC	Rulebook on type approval of permissible sound level (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 70/221/EEC	Rulebook on type approval of fuel tanks/ rear protective devices (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 70/222/EEC	Rulebook on type approval of rear registration plate space (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 70/311/EEC	Rulebook type approval of on steering effort (MoTMA)	LRTS & LTRPCA	IV Q 2018

Directive 70/387/EEC	Rulebook on type approval of door latches and hinges (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 70/388/EEC	Rulebook on type approval of audible warning (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2003/97/EC	Rulebook on type approval of indirect vision devices (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 71/320/EEC	Rulebook on type approval of braking (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 72/245/EEC	Rulebook on type approval of radio interference (EMC) (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/60/EEC	Rulebook on type approval of interior fittings (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/61/EEC	Rulebook on type approval of anti-theft and immobilizer (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/297/EEC	Rulebook on type approval of protective steering (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/408/EEC	Rulebook on type approval of seat strength (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/483/EEC	Rulebook on type approval of exterior projections (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 75 443/EEC	Rulebook on type approval of speedometer and reverse gear (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/114/EEC	Rulebook on type approval of statutory plates (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/115/EEC	Rulebook on type approval of seat belt anchorages (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/756/EEC	Rulebook on type approval of installation of lighting and light signaling devices (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/757/EEC	Rulebook on retro reflectors (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/758/EEC	Rulebook on type approval of end-outline, front position (side), stop, side marker, daytime running lamps (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/759/EEC	Rulebook on type approval of direction indicators (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/760/EEC	Rulebook on type approval of rear registration rear lamps (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/761/EEC	Rulebook on type approval of headlamps (incl. bulbs) (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/762/EEC	Rulebook on type approval of front fog lamps (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/389/EEC	Rulebook on type approval of towing hooks (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/538/EEC	Rulebook on type approval of rear fog lamps (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/539/EEC	Rulebook on type approval of reversing lamps(MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/540/EEC	Rulebook on type approval of parking lamps (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/541/EEC	Rulebook on type approval of seat belts and restraint systems (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/649/EEC	Rulebook on type approval of forward vision (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 78/316/EEC	Rulebook on type approval of identification of controls, tell-tales and indicators (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 78/317/EEC	Rulebook on type approval of defrost/demist (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 78/318/EEC	Rulebook on type approval of wash/wipe (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2001/56/EC	Rulebook on type approval of heating systems (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 78/549/EEC	Rulebook on type approval of wheel guards (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 78/932/EEC	Rulebook on type approval of head restraints (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 80/1269/EEC	Rulebook on type approval of engine power (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2005/55/EC	Rulebook on type approval of emissions (Euro IV and V) heavy duty vehicles (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation EC 595/2009	Rulebook on type approval of Rulebook on emissions (Euro VI) heavy duty vehicles/access to information (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 89/297/EEC	Rulebook on type approval of lateral protection (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 91/226/EEC	Rulebook on type approval of spray suppression systems (MoTMA)	LRTS & LTRPCA	IV Q 2018

Directive 92/21/EEC	Rulebook on type approval of masses and dimensions (cars) (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 92/22/EEC	Rulebook on type approval of safety glazing (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 92/23/EEC	Rulebook on type approval of tyres (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 92/24/EEC	Rulebook on type approval of speed limitation devices (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 97/27/EC	Rulebook on type approval of masses and dimensions (other vehicles than cars) (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 92/114/EEC	Rulebook on type approval of external projections of cars (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 94/20/EC	Rulebook on type approval of couplings (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 95/28/EC	Rulebook on type approval of flammability (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2001/85/EC	Rulebook on type approval of buses and coaches (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 96/79/EC	Rulebook on type approval of frontal impact (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 96/27/EC	Rulebook on type approval of side impact (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 98/91/EC	Rulebook on type approval of vehicles intended for transport of dangerous goods (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2000/40/EC	Rulebook on type approval of front underrun protection (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EC) 78/2009	Rulebook on type approval of pedestrian protection (MoTMA)	LRTS & LTRPCA	IV Q 2017
Directive 2005/64/EC	Rulebook on type approval of recyclability (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2006/40/EC	Rulebook on type approval of air conditioning systems (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EC) 79/2009	Rulebook on type approval of hydrogen system (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EC) 661/2009	Rulebook on type approval of certain component parts and characteristics of motor vehicles (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 65/2012	Rulebook on type approval of gear shift indicators (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 347/2012	Rulebook on type approval of advanced emergency braking system (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 351/2012	Rulebook on type approval of lane departure warning system (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 2015/562	Rulebook on technical requirements for certain categories motor vehicles with regard to advanced emergency braking system (MoTMA)	LRTS & LTRPCA	IV Q 2018

TWO AND THREE WHEELED MOTOR VEHICLES			
Directive 2002/24 (Framework directive)	Rulebook on type approval of two and three wheeled motor vehicles (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/14/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to braking (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/29/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to marking of controls, tell-tales and indicators (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/30/EEC	Rulebook on type approval for audible warning devices on motor vehicles with two or three wheels (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/31/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to stands (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/32/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to handholds for passengers (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/33/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to protection from unauthorized use (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/34/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to statutory inscriptions (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/92/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to installation of lighting and light signaling (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/93/EEC	Rulebook on type approval of motor vehicles with two or three wheels with regard to masses and dimensions (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 93/94/EC	Rulebook on type approval of motor vehicles with two or three wheels with regard to space for rear license plates (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 95/1/EC	Rulebook on type approval of motor vehicles with two or three wheels with regard to maximum speed and maximum power (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 97/24/EC	Rulebook on type approval of certain component parts and characteristics of motor vehicles with two or three wheels (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2000/7/EC	Rulebook on type approval of speedometer on motor vehicles with two or three wheels (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 901/2014	Rulebook on technical requirements for the homologation and market surveillance of two- or three-wheeled vehicles and quadricycles	LRTS & LTRPCA	IV Q 2018

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
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**AGRICULTURAL AND
FORESTRY TRACTORS**

Directive 2003/37/EC (Framework directive)	Rulebook on type approval of agricultural and forestry tractors (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/151/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to maximum permissible gross mass, position and affixing of rear plates, fuel tank, additional weights, sound warning units, allowable noise level and exhaust systems (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/152/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to maximum design speed and load platform (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/346/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to rear view mirrors (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 74/347/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to field of vision and windscreen wipers (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 75/321/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to steering device (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 75/322/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to prevention of electromagnetic interference (EMC) (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 75/443/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to reverse and speedometer (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 75/541/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to safety belts (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/115/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to seat-belt attachment points (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/432/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to braking devices (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 76/763/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to passenger seats (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/311/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to noise level experienced by tractor driver (internal) (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 77/536/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to roll-over protection structure (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 78/764/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to driver's seat (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2000/25/EC	Rulebook on type approval of agricultural and forestry tractors with regard to emission of pollutants from tractor's diesel engines (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 78/933/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to lighting installation (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 79/532/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to lighting and light-signaling devices (MoTMA)	LRTS & LTRPCA	IV Q 2018

Directive 79/533/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to coupling and reverse gear (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 79/622/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to roll-over protection (static testing) (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 80/720/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to operating space and access to driving position (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 86/297/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to power take off (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 86/298/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to rear-mounted roll-over protection of narrow tractors (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 86/415/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to installation of controls (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 87/402/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to front mounted roll-over protection of narrow tractors (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 89/173/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to dimensions and trailer mass, glazing, speed governor, protection of drive components, mechanical couplings, trailer brake coupling and statutory plate (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 89/297/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to lateral protection (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 92/24/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to spray suppression systems (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 91/226/EEC	Rulebook on type approval of agricultural and forestry tractors with regard to speed limitation devices (MoTMA)	LRTS & LTRPCA	IV Q 2018
Directive 2000/25/EC	Rulebook on type approval of agricultural and forestry tractors with regard to pollutant emissions (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 1322/2014	Rulebook on technical requirements with regard to vehicle construction and general requirements for the homologation of agricultural and forestry tractors (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 2015/208	Rulebook on technical requirements regarding vehicle functional safety for the homologation of agricultural and forestry vehicles (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 2015/68	Rulebook on technical requirements regarding vehicle braking performance for the homologation of agricultural and forestry vehicles (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 2015/96	Rulebook on technical requirements as regards environmental and propulsion unit performance of agricultural and forestry tractors (MoTMA)	LRTS & LTRPCA	IV Q 2018
Regulation (EU) 2015/504	Rulebook on technical requirements for homologation and market surveillance of agricultural and forestry tractors (MoTMA)	LRTS & LTRPCA	IV Q 2018
NON-ROAD MOBILE MACHINERY			
Directive 97/68/EEC	Rulebook emissions from non-road mobile machinery (MoTMA)	LRTS & LTRPCA	IV Q 2018

EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
OLD APPROACH TEXTILES, FOOTWEAR AND GLASS			
Regulation (EU) 1007/2011	Rulebook on labeling and marking of textiles (OG MNE 48/14) (MoE)	LTRPCA	
	Amendments of Rulebook on labeling and marking of textiles (MoE)	LTRPCA	IV Q 2017
Directive 94/11/EC	Rulebook on labelling of footwear (OG MNE 48/14) (MoE)	LTRPCA	
	Amendments of Rulebook on labelling of footwear (MoE)	LTRPCA	IV Q 2017
Directive 69/493/EEC	Rulebook on technical requirements on crystal glass (OG MNE 48/14) (MoE)	LTRPCA	

PROCEDURAL MEASURES Cultural Goods			
EU Legal Acts to be Transposed	MN Transposition Legal Act Authority in Charge	Primary Legal Base for By-laws	Adoption Period
Directive 2014/60/EU	Law on amending of the Cultural Property Act (MC)	N/A – primary law	IV Q 2018
	Rulebook on the list of collection of objects that may be considered national treasure of an EU Member State	Cultural Property Act	IV Q 2018
PROCEDURAL MEASURES Possession of Weapon			
Directive 91/477/EEC Directive 2008/51/EC	Law on Weapons (OG MNE 10/15) (MoIA)	N/A – primary law	
	Law on Weapons		IV Q 2018
	Rulebook on detailed procedure for disabling weapons (OG MNE 34/15)		
	Rulebook on detailed manner of training of citizens for the proper use of weapons (OG MNE 34/15)		
	Rulebook on the format of documents on weapons (OG MNE 35/15)		
	Rulebook on the manner of disposal of seized and submitted weapons and ammunition (OG MNE 36/15)		

	Rulebook on conditions for the manufacturing, sale, repair and conversion of weapons and ammunition (OG MNE 43/15)		
	Rulebook on the conditions to be met by civil shooting range (OG MNE 43/15)		
PROCEDURAL MEASURES FOREIGN TRADE AND DUAL USE GOODS¹⁰			
Regulation (EC) 2368/2002	The Law on Amendments to the Law on Foreign Trade (OG MNE 57/14) (MoE)	N/A – primary law	
Regulation (EC) 428/2009 Regulation (EC) 1232/2011 Directive 2009/43/EC 32003E0468 32000E0401 32008E0944	Law on Dual-Use Goods Export Control (OG MNE 30/12) (MoE)	N/A – primary law	
	Law on Dual-Use Goods Export Control (MoE)	N/A – primary law	IV Q 2016
Regulation EU 1382/2014	Decision on establishing national control list of dual-use goods (OG MNE 50/15) (MoE)	Law on Dual-Use Goods Export Control (MoE)	
Regulation EU 2420/2014	Decision on establishing national control list of dual-use goods (MoE)	Law on Dual-Use Goods Export Control (MoE)	II Q 2016
PROCEDURAL MEASURES Goods that can be used for anti-torture - repression – torture			
Regulation EU 1236/2005 Regulation EU 775/2014 Regulation EU 1113/2015	Decision on establishing list of goods that can be used for anti-torture - repression – torture (MoE)		IV Q 2017
PROCEDURAL MEASURES Notification procedure			
Directive 2015/1535	Decree on notification of technical regulation, rules on information society and conformity assessment procedures	LTRPCA	II Q 2018

¹⁰ In addition, an alignment to Directive 2004/17/EC and Directive 2009/81/EC is related to the adoption of the Law on Public Procurement which is subject of Chapter 5

MoE	Ministry of Economy
MoH	Ministry of Health
MoIA	Ministry of Internal Affairs
MoTMA	Ministry of Transport and Maritime Affairs
MoIST	Ministry for Information Society and Telecommunications
MoSDT	Ministry of Sustainable Development and Tourism
MoARD	Ministry of Agriculture and Rural Development
LM	Law on Medicines
LMD	Law on medical devices
LRTS	Law on Road Traffic Safety
LTRPCA	Law on Technical Requirements for Products and Conformity Assessment
LCPCS	Law on Amendments to Law on Control of Production and Circulation of Substances Used in Manufacture of Narcotic Drugs and Psychotropic Substances

