

ANNEX XVI

LIST OF LEGISLATION WITH A TIMETABLE FOR ITS APPROXIMATION ⁽¹⁾

Union legislation	Deadline for approximation
HORIZONTAL LEGISLATIVE FRAMEWORK FOR MARKETING OF PRODUCTS	
Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products	Approximated on the date of entry into force of the Law No 235 of 1 December 2011
Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety	Review and full approximation: 2014
Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products	Approximation: 2012
Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation	Approximation: 2015
Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement as amended by Directive 2009/3/EC of the European Parliament and of the Council	Approximation: 2015
LEGISLATION BASED ON THE PRINCIPLES OF THE NEW APPROACH WHICH PROVIDE FOR CE MARKING	
Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits	Review and full approximation: 2015
Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels	Approximation: 2015
Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products	Full approximation: 2015
Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility	Review and full approximation: 2015
Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment	Review and full approximation: 2015
Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels	Review and full approximation: 2016
Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons	Approximation: 2015

⁽¹⁾ For the purposes of this Annex and of Article 173(2) of this Agreement, references to the Union *acquis* or legislation or to specific Union acts shall be understood to cover any past or future revisions of the relevant acts as well as any implementation measures related to those acts.

Union legislation	Deadline for approximation
Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres	Review and full approximation: 2015
Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses Commission Decision 2004/388/EC of 15 April 2004 on an Intra-Community transfer of explosives document Commission Directive 2008/43/EC of 4 April 2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the identification and traceability of explosives for civil uses	Review and full approximation: 2015
European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts	Review and full approximation: 2016
Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery	Approximation: 2015
Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments	Approximation: 2014
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on <i>in vitro</i> diagnostic medical devices	Review and full approximation: 2015
Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels	Full approximation: 2017
Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments as amended by Regulation (EU) No 1025/2012 of the European Parliament and of the Council in order to align it with the model provisions of Decision 768/2008/EC	Full approximation: 2014
Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment	Review and full approximation: 2017
Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity	Review and full approximation: 18 months after the entry into force of this Agreement
Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft	Approximation: 2015
Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys	Review and full approximation: 2015
Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles	Approximation: 2015

Union legislation	Deadline for approximation
DIRECTIVES BASED ON THE PRINCIPLES OF THE NEW APPROACH OR THE GLOBAL APPROACH, BUT WHICH DO NOT PROVIDE FOR CE MARKING	
European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	Approximation: 2015
Council Directive 1999/36/EC of 29 April 1999 on transportable pressure equipment	Approximation: 2016
COSMETIC PRODUCTS	
Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products	Approximation: 2015
First Commission Directive 80/1335/EEC of 22 December 1980 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products	Approximation: 2015
Second Commission Directive 82/434/EEC of 14 May 1982 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products	
Third Commission Directive 83/514/EEC of 27 September 1983 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products	
Fourth Commission Directive 85/490/EEC of 11 October 1985 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products	
Fifth Commission Directive 93/73/EEC of 9 September 1993 on the methods of analysis necessary for checking composition of cosmetic products	
Sixth Commission Directive 95/32/EC of 7 July 1995 relating to methods of analysis necessary for checking the composition of cosmetic products	
Seventh Commission Directive 96/45/EC of 2 July 1996 relating to methods of analysis necessary for checking the composition of cosmetic products	
CONSTRUCTION OF MOTOR VEHICLES	
1. Motor vehicles and their trailers	
1.1 Type-approval	
Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)	Approximation: 2016
1.2 Harmonised technical requirements	
Regulation (EC) No 78/2009 of the European Parliament and of the Council of 14 January 2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users	Approximation: 2017

Union legislation	Deadline for approximation
Regulation (EC) No 79/2009 of the European Parliament and of the Council of 14 January 2009 on type-approval of hydrogen-powered motor vehicles	Approximation: 2017
Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information	Approximation: 2018
Commission Regulation (EC) No 692/2008 of 18 July 2008 implementing and amending Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information	Approximation: 2018
Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor	Approximation: 2018
Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information	Approximation: 2018
Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability	Approximation: 2018
Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles	Approximation: 2015

2. Two- or three-wheel motor vehicles

2.1 Type-approval

Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles	Approximation: 2015
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2.2 Harmonised technical requirements

Council Directive 93/14/EEC of 5 April 1993 on the braking of two- or three-wheel motor vehicles	Approximation: 2017
Directive 2009/80/EC of the European Parliament and of the Council of 13 July 2009 on the identification of controls, tell-tales and indicators for two or three-wheel motor vehicles	Approximation: 2017
Council Directive 93/30/EEC of 14 June 1993 on audible warning devices for two- or three-wheel motor vehicles	Approximation: 2017
Directive 2009/78/EC of the European Parliament and of the Council of 13 July 2009 on stands for two-wheel motor vehicles	Approximation: 2017
Directive 2009/79/EC of the European Parliament and of the Council of 13 July 2009 on passenger hand-holds on two-wheel motor vehicles	Approximation: 2017

Union legislation	Deadline for approximation
Council Directive 93/33/EEC of 14 June 1993 on protective devices intended to prevent the unauthorized use of two or three-wheel motor vehicles	Approximation: 2017
Directive 2009/139/EC of the European Parliament and of the Council of 25 November 2009 on statutory markings for two- or three-wheel motor vehicles	Approximation: 2017
Directive 2009/67/EC of the European Parliament and of the Council of 13 July 2009 on the installation of lighting and light-signalling devices on two or three-wheel motor vehicles	Approximation: 2017
Council Directive 93/93/EEC of 29 October 1993 on the masses and dimensions of two or three-wheel motor vehicles	Approximation: 2017
Directive 2009/62/EC of the European Parliament and of the Council of 13 July 2009 relating to the space for mounting the rear registration plate of two or three-wheel motor vehicles	Approximation: 2017
Directive 95/1/EC of the European Parliament and of the Council of 2 February 1995 on the maximum design speed, maximum torque and maximum net engine power of two or three-wheel motor vehicles	Approximation: 2017
Directive 97/24/EC of the European Parliament and of the Council of 17 June 1997 on certain components and characteristics of two or three-wheel motor vehicles	Approximation: 2017
Directive 2000/7/EC of the European Parliament and of the Council of 20 March 2000 on speedometers for two- or three-wheel motor vehicles	Approximation: 2017

3. Wheeled agricultural or forestry tractors

3.1 Type-approval

Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units	Approximation: 2016
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3.2 Harmonised technical requirements

Directive 2009/63/EC of the European Parliament and of the Council of 13 July 2009 on certain parts and characteristics of wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/60/EC of the European Parliament and of the Council of 13 July 2009 on the maximum design speed of and load platforms for wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/59/EC of the European Parliament and of the Council of 13 July 2009 on rear-view mirrors for wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2008/2/EC of the European Parliament and of the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/66/EC of the European Parliament and of the Council of 13 July 2009 on the steering equipment of wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/64/EC of the European Parliament and of the Council of 13 July 2009 on the suppression of radio interference produced by agricultural or forestry tractors (electromagnetic compatibility)	Approximation: 2016

Union legislation	Deadline for approximation
Council Directive 76/432/EEC of 6 April 1976 on the approximation of the laws of the Member States relating to the braking devices of wheeled agricultural or forestry tractors	Approximation: 2016
Council Directive 76/763/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to passenger seats for wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/76/EC of the European Parliament and of the Council of 13 July 2009 relating to the driver-perceived noise level of wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/57/EC of the European Parliament and of the Council of 13 July 2009 relating to the roll-over protection structures of wheeled agricultural or forestry tractors	Approximation: 2016
Council Directive 77/537/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors	Approximation: 2016
Council Directive 78/764/EEC of 25 July 1978 on the approximation of the laws of the Member States relating to the driver's seat on wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/61/EC of the European Parliament and of the Council of 13 July 2009 relating to the installation of lighting and light-signalling devices on wheeled agricultural and forestry tractors	Approximation: 2016
Directive 2009/68/EC of the European Parliament and of the Council of 13 July 2009 on the component type-approval of lighting and light-signalling devices on wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/58/EC of the European Parliament and of the Council of 13 July 2009 on the coupling device and the reverse of wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2009/75/EC of the European Parliament and of the Council of 13 July 2009 on roll-over protection structures of wheeled agricultural or forestry tractors (static testing)	Approximation: 2016
Council Directive 80/720/EEC of 24 June 1980 on the approximation of the laws of the Member States relating to the operating space, access to the driving position and the doors and windows of wheeled agricultural or forestry tractors	Approximation: 2016
Council Directive 86/297/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to power take-offs of wheeled agricultural or forestry tractors and their protection	Approximation: 2016
Council Directive 86/298/EEC of 26 May 1986 on rear-mounted roll-over protection structures of narrow-track wheeled agricultural and forestry tractors	Approximation: 2016
Council Directive 86/415/EEC of 24 July 1986 on the installation, location, operation and identification of the controls of wheeled agricultural or forestry tractors	Approximation: 2016
Council Directive 87/402/EEC of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors	Approximation: 2016

Union legislation	Deadline for approximation
Council Directive 89/173/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to certain components and characteristics of wheeled agricultural or forestry tractors	Approximation: 2016
Directive 2000/25/EC of the European Parliament and of the Council of 22 May 2000 on action to be taken against the emission of gaseous and particulate pollutants by engines intended to power agricultural or forestry tractors	Approximation: 2016

CHEMICALS

1. REACH and REACH implementation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency	Approximation: 2013- 2014
Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Approximation: 2013-2014

2. Dangerous chemicals

Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals	Approximation: 2016
Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances	Approximation: 2016
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment	Approximation: 2014
Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)	Approximation: 2016
Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators	Approximation: 2013-2014
Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)	Approximated in 2009
Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants	Approximation: 2013-2014

3. Classification, packaging and labelling

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures	Approximation: 2013-2014
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4. Detergents

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents	Approximation: 2013-2014
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Union legislation	Deadline for approximation
5. Fertilisers	
Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers	Approximated on 11 June 2013
6. Drug precursors	
Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors	Approximation: 2015
7. Good laboratory practice	
Application of principles and verification for tests on chemicals, inspection and verification of good laboratory practice	
Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances	Approximation: 2015
Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)	Approximation: 2013-2014
PHARMACEUTICALS	
1. Medicinal products for human use	
Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems	Approximation: 2014
Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use	Transposition: 2015
2. Medicinal products for veterinary use	
Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products	Approximation: 2013
Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription	Approximation: 2014
3. Miscellaneous	
Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	Approximation: 2014
Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms	Approximation: 2015
Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products	Approximation: 2015

Union legislation	Deadline for approximation
Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms	Approximation: 2015
Commission Regulation (EC) No 540/95 of 10 March 1995 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93	Approximation: 2015
Commission Regulation (EC) No 1662/95 of 7 July 1995 laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorisations for products for human or veterinary use	Approximation: 2015
Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93	Approximation: 2015
Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products	Approximation: 2015