

**ANNEX XVI****LIST OF LEGISLATION  
WITH A TIMETABLE FOR ITS APPROXIMATION<sup>1</sup>**

| <b>Union legislation</b>                                                                                                                                                                                                                                                                                                                          | <b>Deadline for approximation</b>                                                  |
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| <b>HORIZONTAL LEGISLATIVE FRAMEWORK FOR MARKETING OF PRODUCTS</b>                                                                                                                                                                                                                                                                                 |                                                                                    |
| 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<br>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:<br>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:<br>2012                                                             |
| Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation                                                                                                                                                                                                                         | Approximation:<br>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:<br>2015                                                             |

<sup>1</sup> 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.

| <b>LEGISLATION BASED ON THE PRINCIPLES OF THE NEW APPROACH WHICH PROVIDE FOR CE MARKING</b>                                                                                                                                           |                                        |
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| 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:<br>2015 |
| Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels                                                                                                          | Approximation:<br>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:<br>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:<br>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:<br>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:<br>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:<br>2015                 |
| 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:<br>2015 |

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| <p>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</p> <p>Commission Decision 2004/388/EC of 15 April 2004 on an Intra-Community transfer of explosives document</p> <p>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</p> | <p>Review and full approximation:<br/>2015</p> |
| <p>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</p>                                                                                                                                                                                                                                                                                                                                    | <p>Review and full approximation:<br/>2016</p> |
| <p>Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery</p>                                                                                                                                                                                                                                                                                                                                                                                | <p>Approximation:<br/>2015</p>                 |
| <p>Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments</p>                                                                                                                                                                                                                                                                                                                                                                  | <p>Approximation:<br/>2014</p>                 |
| <p>Council Directive 93/42/EEC of 14 June 1993 concerning medical devices</p> <p>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</p> <p>Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on <i>in vitro</i> diagnostic medical devices</p>                                                                                                      | <p>Review and full approximation:<br/>2015</p> |
| <p>Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels</p>                                                                                                                                                                                                                                                                                                                                            | <p>Full approximation:<br/>2017</p>            |

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| 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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>2015                                                                   |

| <b>DIRECTIVES BASED ON THE PRINCIPLES OF THE NEW APPROACH OR THE GLOBAL APPROACH, BUT WHICH DO NOT PROVIDE FOR CE MARKING</b>                                                                                |                        |
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| European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste                                                                                                      | Approximation:<br>2015 |
| Council Directive 1999/36/EC of 29 April 1999 on transportable pressure equipment                                                                                                                            | Approximation:<br>2016 |
| <b>COSMETIC PRODUCTS</b>                                                                                                                                                                                     |                        |
| Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products                                                                                          | Approximation:<br>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:<br>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  |                        |

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| 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                                                                                                                                |                        |
| <b>CONSTRUCTION OF MOTOR VEHICLES</b>                                                                                                                                                                                                                                           |                        |
| <b>1. Motor vehicles and their trailers</b>                                                                                                                                                                                                                                     |                        |
| <b>1.1 Type-approval</b>                                                                                                                                                                                                                                                        |                        |
| 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:<br>2016 |
| <b>1.2 Harmonised technical requirements</b>                                                                                                                                                                                                                                    |                        |
| 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:<br>2017 |
| 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:<br>2017 |

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| 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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>2015 |

| <b>2. Two- or three-wheel motor vehicles</b>                                                                                                                                          |                        |
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| <b>2.1 Type-approval</b>                                                                                                                                                              |                        |
| 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:<br>2015 |
| <b>2.2 Harmonised technical requirements</b>                                                                                                                                          |                        |
| Council Directive 93/14/EEC of 5 April 1993 on the braking of two- or three-wheel motor vehicles                                                                                      | Approximation:<br>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:<br>2017 |
| Council Directive 93/30/EEC of 14 June 1993 on audible warning devices for two- or three-wheel motor vehicles                                                                         | Approximation:<br>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:<br>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:<br>2017 |
| 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:<br>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:<br>2017 |

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| 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:<br>2017 |
| Council Directive 93/93/EEC of 29 October 1993 on the masses and dimensions of two or three-wheel motor vehicles                                                                                                                                                  | Approximation:<br>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:<br>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:<br>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:<br>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:<br>2017 |
| <b>3. Wheeled agricultural or forestry tractors</b>                                                                                                                                                                                                               |                        |
| <b>3.1 Type-approval</b>                                                                                                                                                                                                                                          |                        |
| 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:<br>2016 |

| <b>3.2 Harmonised technical requirements</b>                                                                                                                                                              |                        |
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| 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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>2016 |
| 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:<br>2016 |

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| 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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>2016 |

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| 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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>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:<br>2016 |
| 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:<br>2016 |

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| 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:<br>2016       |
| <b>CHEMICALS</b>                                                                                                                                                                                                                                       |                              |
| <b>1. REACH and REACH implementation</b>                                                                                                                                                                                                               |                              |
| 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:<br>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:<br>2013-2014  |
| <b>2. Dangerous chemicals</b>                                                                                                                                                                                                                          |                              |
| 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:<br>2016       |
| Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances                                                                                                                                  | Approximation:<br>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:<br>2014       |

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| Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)                            | Approximation:<br>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:<br>2013-2014     |
| Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)                                | Approximated<br>in 2009         |
| Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants                                          | Approximation:<br>2013-2014     |
| <b>3. Classification, packaging and labelling</b>                                                                                                                    |                                 |
| 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:<br>2013-2014     |
| <b>4. Detergents</b>                                                                                                                                                 |                                 |
| Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents                                                             | Approximation:<br>2013-2014     |
| <b>5. Fertilisers</b>                                                                                                                                                |                                 |
| Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers                                                | Approximated<br>on 11 June 2013 |
| <b>6. Drug precursors</b>                                                                                                                                            |                                 |
| Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors                                                     | Approximation:<br>2015          |

| <b>7. Good laboratory practice</b><br><b>Application of principles and verification for tests on chemicals, inspection and verification of good laboratory practice</b>                                                                                                                                              |                             |
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| 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:<br>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:<br>2013-2014 |
| <b>PHARMACEUTICALS</b>                                                                                                                                                                                                                                                                                               |                             |
| <b>1. Medicinal products for human use</b>                                                                                                                                                                                                                                                                           |                             |
| 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:<br>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:<br>2015      |
| <b>2. Medicinal products for veterinary use</b>                                                                                                                                                                                                                                                                      |                             |
| 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:<br>2013      |

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| 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:<br>2014 |
| <b>3. Miscellaneous</b>                                                                                                                                                                                                                                                                                                                                      |                        |
| 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:<br>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:<br>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:<br>2015 |
| 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:<br>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:<br>2015 |

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| 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:<br>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:<br>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:<br>2015 |

## **ANNEX XVII**

### **COVERAGE**

**ANNEX XVII-A****SPS MEASURES****Part 1****Measures applicable to main live animal categories**

- I. Equidae (including zebras) or asinine species or the offspring of crossing of those species
- II. Bovine animals (including *Bubalus bubalis* and *Bison*)
- III. Ovine and caprine animals
- IV. Porcine animals
- V. Poultry (including fowl, turkeys, guinea fowl, ducks, geese)
- VI. Live fish
- VII. Crustaceans
- VIII. Molluscs
- IX. Eggs and gametes of live fish
- X. Hatching eggs
- XI. Semen-ova-embryos
- XII. Other mammals
- XIII. Other birds
- XIV. Reptiles
- XV. Amphibians
- XVI. Other vertebrates
- XVII. Bees

## **Part 2**

### **Measures applicable to animal products**

#### **I. Main product categories of animal products for human consumption**

1. Fresh meat of domestic ungulates, poultry and lagomorphs, farm and wild game, including offal
2. Minced meat, meat preparations, mechanically separated meat (MSM), meat products
3. Live bivalve molluscs
4. Fishery products
5. Raw milk, colostrum, dairy products and colostrum-based products
6. Eggs and eggs products
7. Frogs' legs and snails
8. Rendered animal fats and greaves
9. Treated stomachs, bladders and intestines
10. Gelatine, raw material for the production of gelatine for human consumption
11. Collagen
12. Honey and apicultural products

**II Main products' categories of animal by-products:**

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| In slaughterhouses                                                                                             | Animal by-products to be fed to fur animals                                                                                                  |
|                                                                                                                | Animal by-products for the manufacture of pet food                                                                                           |
|                                                                                                                | Blood and blood products from equidae to be used outside the feed chain                                                                      |
|                                                                                                                | Fresh or chilled hides and skins of ungulates                                                                                                |
|                                                                                                                | Animal by-products for the manufacture of derived products for uses outside the feed chain                                                   |
| In dairy plants                                                                                                | Milk, milk-based products and milk-derived products                                                                                          |
|                                                                                                                | Colostrum and colostrum products                                                                                                             |
| In other facility for the collection or handling of animal by-products (i.e. unprocessed/ untreated materials) | Blood and blood products from equidae to be used outside the feed chain                                                                      |
|                                                                                                                | Untreated blood products, excluding of equidae, for derived products for purposes outside the feed chain for farmed animals                  |
|                                                                                                                | Treated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals |
|                                                                                                                | Fresh or chilled hides and skins of ungulates                                                                                                |

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|                      | Pig bristles from third countries or regions thereof that are free from African swine fever                                                                                                                                |
|                      | Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) for uses other than as feed material, organic fertilizer or soil improvers |
|                      | Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, for the production of organic fertilizers or soil improvers                                                               |
|                      | Gelatine not intended for human consumption to be used by the photographic industry                                                                                                                                        |
|                      | Wool and hair                                                                                                                                                                                                              |
|                      | Treated feathers, parts of feathers and down                                                                                                                                                                               |
| In processing plants | Processed animal protein, including mixtures and products other than pet food containing such protein                                                                                                                      |
|                      | Blood products that could be used as feed material                                                                                                                                                                         |
|                      | Treated hides and skins of ungulates                                                                                                                                                                                       |
|                      | Treated hides and skins of ruminants and of equidae (21 days)                                                                                                                                                              |
|                      | Pig bristles from third countries or regions thereof that are not free of African swine fever                                                                                                                              |
|                      | Fish oil to be used as feed material or for purposes outside the feed chain                                                                                                                                                |
|                      | Rendered fats to be used as feed materials                                                                                                                                                                                 |

|                                                                                     |                                                                                                                                               |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                     | Rendered fats for certain purposes outside the feed chain for farmed animals                                                                  |
|                                                                                     | Gelatine or Collagen to be used as feed material or for purposes outside the feed chain                                                       |
|                                                                                     | Hydrolysed protein, Dicalcium phosphate or Tricalcium phosphate to be used as feed material or for purposes outside the feed chain            |
|                                                                                     | Apiculture by-products intended exclusively for use in apiculture                                                                             |
|                                                                                     | Fat derivatives to be used outside the feed chain                                                                                             |
|                                                                                     | Fat derivatives to be used as feed or outside the feed chain                                                                                  |
|                                                                                     | Egg products that could be used as feed material                                                                                              |
| In pet food plants (including plants manufacturing dogchews and flavouring innards) | Canned pet food                                                                                                                               |
|                                                                                     | Processed pet food other than canned pet food                                                                                                 |
|                                                                                     | Dogchews                                                                                                                                      |
|                                                                                     | Raw pet food for direct sale                                                                                                                  |
|                                                                                     | Flavouring innards for use in the manufacture of pet food                                                                                     |
| In game trophies plants                                                             | Treated game trophies and other preparations of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins |
|                                                                                     | Game trophies or other preparations of birds and ungulates consisting of entire parts not having been treated                                 |

|                                                                 |                                                                                                      |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| In plants or establishments manufacturing intermediate products | Intermediate products                                                                                |
| Fertiliser and soil improvers                                   | Processed animal protein including mixtures and products other than pet food containing such protein |
|                                                                 | Processed manure, derived products from processed manure and guano from bats                         |
| In storage of derived products                                  | All derived products                                                                                 |

### III. Pathogenic agents

#### Part 3

#### Plants, plant products and other objects

Plants, plant products and other objects<sup>1</sup> which are potential carriers of pests that, by their nature or that of their processing, may create a risk for the introduction and spread of pests

---

<sup>1</sup> Packaging, conveyances, containers, soil and growing mediums and any other organisms, object or material capable of harbouring or spreading pests.

## **Part 4**

### **Measures applicable to food and feed additives**

Food:

1. Food additives (all food additives and colours);
2. Processing aids;
3. Food flavourings;
4. Food enzymes.

Feed<sup>1</sup>:

5. Feed additives;
  6. Feed materials;
  7. Compound feed and pet food except if covered by Part 2 (II);
  8. Undesirable substances in feed.
- 

---

<sup>1</sup> Only animal by-products originated from animals or parts of animals, declared as fit for human consumption may enter into the feed chain of farmed animals.

## **ANNEX XVII-B**

### **ANIMAL WELFARE STANDARDS**

Animal welfare standards concerning:

1. stunning and slaughter of animals;
  2. transport of animals and related operations;
  3. farming animals.
-

## **ANNEX XVII-C**

### **OTHER MEASURES COVERED BY CHAPTER 4 OF TITLE V**

1. Chemicals originating from the migration of substances from packaging materials;
  2. Composite products;
  3. Genetically Modified Organisms (GMOs);
  4. Growth promoting hormones, thyreostatics, certain hormones and B-agonists.
-

## **ANNEX XVII-D**

### **MEASURES TO BE INCLUDED AFTER THE APPROXIMATION OF THE LEGISLATION**

1. Chemicals for decontamination of food;
  2. Cloning;
  3. Irradiation (ionisation).
-

## **ANNEX XVIII**

### **LIST OF NOTIFIABLE ANIMAL AND AQUACULTURE DISEASES AND REGULATED PESTS FOR WHICH REGIONAL FREEDOM CAN BE RECOGNISED**

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**ANNEX XVIII-A****ANIMAL AND FISH DISEASES SUBJECT TO NOTIFICATION,  
FOR WHICH THE STATUS OF THE PARTIES IS RECOGNISED  
AND FOR WHICH REGIONALISATION DECISIONS MAY BE TAKEN**

1. Foot-and-mouth disease
  2. Swine vesicular disease
  3. Vesicular stomatitis
  4. African horse sickness
  5. African swine fever
  6. Bluetongue
  7. Pathogenic Avian influenza
  8. Newcastle disease (NCD)
  9. Rinderpest
  10. Classical swine fever
  11. Contagious bovine pleuro-pneumonia
  12. Peste des petits ruminants
  13. Sheep and goat pox
  14. Rift Valley fever
  15. Lumpy skin disease
  16. Venezuelan equine encephalomyelitis
  17. Glanders
  18. Dourine
  19. Enterovirus encephalomyelitis
  20. Infectious haematopoietic necrosis (IHN)
  21. Viral haemorrhagic septicaemia (VHS)
  22. Infectious Salmon Anaemia (ISA)
  23. Bonamia ostreae
  24. Marteilia refringens
-

**ANNEX XVIII-B****RECOGNITION OF THE PEST STATUS, PEST FREE AREAS OR PROTECTED ZONES****A. Recognition of pest status**

Each Party shall establish and communicate a list of regulated pests based on the following principles:

1. Pests not known to occur within any part of its own territory;
2. Pests known to occur within any part of its own territory and under official control;
3. Pests known to occur within any part of its own territory, under official control and for which pest free areas or protected zones are established.

Any change to the list of pest status shall be immediately notified to the other Party unless otherwise notified to the relevant international organization.

**B. Recognition of Pest Free Areas (PFAs) and protected zones**

The Parties recognise the protected zones and the concept of PFAs, and its application in respect of relevant ISPMs.

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## **ANNEX XIX**

### **REGIONALISATION/ZONING, PEST-FREE AREAS AND PROTECTED ZONES**

#### **A. Animal and aquaculture diseases**

##### **1. Animal diseases**

The basis for recognition of the animal disease status of the territory or of a region of a Party shall be the Terrestrial Animal Health Code of the OIE. The basis for regionalisation decisions for an animal disease shall be the Terrestrial Animal Health Code of the OIE.

##### **2. Aquaculture diseases**

The basis for regionalisation decisions for aquaculture diseases shall be the Aquatic Animal Health Code of the OIE.

#### **B. Pests**

The criteria for the establishment of pest free areas or protected zones for certain pests shall comply with the provisions of either:

- the FAO International Standard for Phytosanitary Measures No 4 on Requirements for the establishment of pest free areas and the definitions of the relevant ISPMs, or
- Article 2(1)(h) of Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community

- C. Criteria for the recognition of the special status for animal diseases of the territory or a region of a Party
1. Where the importing Party considers that its territory or part of its territory is free from an animal disease other than a disease listed in Annex XVIII-A to this Agreement, it shall present to the exporting Party appropriate supporting documentation, setting out in particular the following criteria:
    - the nature of the disease and the history of its occurrence in its territory;
    - the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation and on the fact that the disease must by law be notified to the competent authorities;
    - the period over which the surveillance was carried out;
    - where applicable, the period during which vaccination against the disease has been prohibited and the geographical area concerned by the prohibition;
    - the arrangements for verifying the absence of the disease.
  2. The additional guarantees, general or specific, which may be required by the importing Party must not exceed those, which the importing Party implements nationally.
  3. The Parties shall notify each other of any change in the criteria specified in paragraph 1 of this point which relate to the disease. The additional guarantees defined in accordance with paragraph 2 of this point may, in the light of such notification, be amended or withdrawn by the SPS Sub-Committee.
-

## **ANNEX XX**

### **PROVISIONAL APPROVAL OF ESTABLISHMENTS**

Conditions and provisions for provisional approval of establishments

1. Provisional approval of establishments means that for the purpose of import the importing Party approves provisionally the establishments in the exporting Party on the basis of appropriate guarantees provided by that Party without prior inspection by the importing Party of the individual establishments in accordance with the provisions of paragraph 4 of this Annex. The procedure and conditions set out in paragraph 4 of this Annex shall be used for modifying or completing the lists provided for in paragraph 2 of this Annex to take account of new applications and guarantees received. Verification may be part of the procedure, only as regards the initial list of establishments, in accordance with the provisions of paragraph 4(d).

2. The provisional approval shall initially be applied to the following categories of establishments

2.1. Establishments for products of animal origin for human consumption:

- Slaughterhouses for fresh meat of domestic ungulates, poultry, lagomorphs and farm game (Annex XVII-A, Part 1)
- Game handling establishments
- Cutting plants
- Establishments for minced meat, meat preparation, mechanically separated meat and meat products
- Purification centres and dispatched centres for live bivalve molluscs
- Establishments for:
  - eggs products
  - dairy products
  - fishery products
  - treated stomachs, bladders and intestines
  - gelatine and collagen
  - fish oil
- Factory vessels
- Freezer vessels

## 2.2 Approved or registered establishments producing animal by-products and main categories of animal by-products not for human consumption

| Type of approved or registered establishment and plants | Product                                                                                    |
|---------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Slaughterhouses                                         | Animal by-products to be fed to fur animals                                                |
|                                                         | Animal by-products for the manufacture of pet food                                         |
|                                                         | Blood and blood products from equidae to be used outside the feed chain                    |
|                                                         | Fresh or chilled hides and skins of ungulates                                              |
|                                                         | Animal by-products for the manufacture of derived products for uses outside the feed chain |
| Dairy plants                                            | Milk, milk-based products and milk-derived products                                        |
|                                                         | Colostrum and colostrum products                                                           |

| Type of approved or registered establishment and plants                                                     | Product                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Other facility for the collection or handling of animal by-products (i.e. unprocessed/ untreated materials) | Blood and blood products from equidae to be used outside the feed chain                                                                                                                                                    |
|                                                                                                             | Untreated blood products, excluding of equidae, for derived products for purposes outside the feed chain for farmed animals                                                                                                |
|                                                                                                             | Treated blood products, excluding of equidae, for the manufacture of derived products for purposes outside the feed chain for farmed animals                                                                               |
|                                                                                                             | Fresh or chilled hides and skins of ungulates                                                                                                                                                                              |
|                                                                                                             | Pig bristles from third countries or regions thereof that are free from African swine fever                                                                                                                                |
|                                                                                                             | Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) for uses other than as feed material, organic fertiliser or soil improvers |
|                                                                                                             | Horns and horn products, excluding horn meal, and hooves and hoof products, excluding hoof meal, for the production of organic fertilisers or soil improvers                                                               |
|                                                                                                             | Gelatine not intended for human consumption to be used by the photographic industry                                                                                                                                        |
|                                                                                                             | Wool and hair                                                                                                                                                                                                              |
|                                                                                                             | Treated feathers, parts of feathers and down                                                                                                                                                                               |

| Type of approved or registered establishment and plants | Product                                                                                               |
|---------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Processing plants                                       | Processed animal protein, including mixtures and products other than pet food containing such protein |
|                                                         | Blood products that could be used as feed material                                                    |
|                                                         | Treated hides and skins of ungulates                                                                  |
|                                                         | Treated hides and skins of ruminants and of equidae (21 days)                                         |
|                                                         | Pig bristles from third countries or regions thereof that are not free of African swine fever         |
|                                                         | Fish oil to be used as feed material or for purposes outside the feed chain                           |
|                                                         | Rendered fats to be used as feed materials                                                            |
|                                                         | Rendered fats for certain purposes outside the feed chain for farmed animals                          |
|                                                         | Gelatine or Collagen to be used as feed material or for purposes outside the feed chain               |

| Type of approved or registered establishment and plants                          | Product                                                                                                                                       |
|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                  | Hydrolysed protein, Dicalcium phosphate or Tricalcium phosphate to be used as feed material or for purposes outside the feed chain            |
|                                                                                  | Apiculture by-products intended exclusively for use in apiculture                                                                             |
|                                                                                  | Fat derivatives to be used outside the feed chain                                                                                             |
|                                                                                  | Fat derivatives to be used as feed or outside the feed chain                                                                                  |
|                                                                                  | Egg products that could be used as feed material                                                                                              |
| Pet food plants (including plants manufacturing dogchews and flavouring innards) | Canned pet food                                                                                                                               |
|                                                                                  | Processed pet food other than canned pet food                                                                                                 |
|                                                                                  | Dogchews                                                                                                                                      |
|                                                                                  | Raw pet food for direct sale                                                                                                                  |
|                                                                                  | Flavouring innards for use in the manufacture of pet food                                                                                     |
| Game trophies plants                                                             | Treated game trophies and other preparations of birds and ungulates, being solely bones, horns, hooves, claws, antlers, teeth, hides or skins |
|                                                                                  | Game trophies or other preparations of birds and ungulates consisting of entire parts not having been treated                                 |

| Type of approved or registered establishment and plants      | Product                                                                                              |
|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Plants or establishments manufacturing intermediate products | Intermediate products                                                                                |
| Fertiliser and soil improvers                                | Processed animal protein including mixtures and products other than pet food containing such protein |
|                                                              | Processed manure, derived products from processed manure and guano from bats                         |
| Storage of derived products                                  | All derived products                                                                                 |

3. The importing Party shall draw up lists of provisionally approved establishments as referred to in paragraphs 2.1 and 2.2 and shall make these lists publicly available.
4. Conditions and procedures for provisional approval:
  - (a) If import of the animal product concerned from the exporting Party has been authorised by the importing Party and the relevant import conditions and certification requirements for the products concerned have been established;

- (b) If the competent authority of the exporting Party has provided the importing Party with satisfactory guarantees that the establishments appearing on its list or lists meet the relevant health requirements of the importing Party and has officially approved the establishment appearing on the lists for exportation to the importing Party;
- (c) In the event of non-compliance with the said guarantees the competent authority of the exporting Party must have a real power to suspend the activities of exportation to the importing Party from an establishment for which that authority provided guarantees;
- (d) Verification in accordance with the provisions of Article 188 of this Agreement by the importing Party may be part of the provisional approval procedure. This verification concerns the structure and the organisation of the competent authority responsible for the approval of the establishment as well as the powers available to that competent authority and the guarantees that it can provide in regard to the implementation of importing Party's rules. The verification may include on the spot inspection of a certain representative number of establishments appearing on the list or lists provided by the exporting Party.

Taking into account the specific structure and division of competence within the Union, such verification in the Union may concern individual Member States.

- (e) Based on the results of the verification provided for in point (d) of this paragraph, the importing Party may amend the existing list of establishments.

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## **ANNEX XXI**

### **PROCESS OF RECOGNITION OF EQUIVALENCE**

#### **1. Principles**

- (a) Equivalence can be determined for an individual measure, or a group of measures, or a system related to a certain commodity, or a category of commodities or all of them;
- (b) The examination by the importing Party of a request for recognition of equivalence of measures pertaining to a certain commodity of the exporting Party shall not be a reason to disrupt trade or suspend on-going imports from the exporting Party of the commodity in question;
- (c) The process of recognition of equivalence of measures is an interactive process between the exporting Party and the importing Party. The process consists of an objective demonstration of equivalence of individual measures by the exporting Party and an objective assessment of the equivalence with a view to the possible recognition of equivalence by the importing Party;
- (d) The final recognition of equivalence of the relevant measures of the exporting Party rests solely with the importing Party.

## 2. Preconditions

- (a) The process depends on the health or pest status, the law and the effectiveness of the inspection and control system related to the commodity in the exporting Party. To this end the law in the sector concerned shall be taken into account, as well as the structure of the competent authority of the exporting Party, the command chain, the authority, the operational procedures and resources, and the effectiveness of the competent authorities as regards inspection and control systems, including the level of enforcement related to the commodity and the regularity and the rapidity of information flow to the importing Party in case of identified hazards. This recognition may be supported by documentation, verification and documents, reports and information related to past experiences, assessment and verifications;
- (b) The Parties may initiate the process of recognition of equivalence pursuant to Article 183 of this Agreement after the successful completion of the regulatory approximation of a measure, a group of measures or a system included in the approximation list set out in Article 181(4) of this Agreement;
- (c) The exporting Party shall only initiate the process when no safeguard measures imposed by the importing Party apply to the exporting Party as regards the commodity.

### 3. The process

- (a) The exporting Party initiates the process by submitting to the importing Party a request for recognition of equivalence of an individual measure or groups of measures or a system for a commodity or a category of commodities in a sector or sub-sector or all of them;
- (b) When appropriate, this request includes also the request and the required documentation for approval by the importing Party on the basis of equivalence of any programme or plan of the exporting Party required by the importing Party and /or the status of approximation as laid down in Annex XXIV to this Agreement regarding the measures or systems described in point (a) of this paragraph as a condition for allowing import of that commodity or a category of commodities;
- (c) With this request, the exporting Party:
  - (i) explains the importance for trade of that commodity or a category of commodities;
  - (ii) identifies the individual measure(s) with which it can comply from all the measures expressed in the import conditions of the importing Party applicable to that commodity or a category of commodities;
  - (iii) identifies the individual measure(s) for which it seeks equivalence out of the total of the measures expressed in the import conditions of the importing Party, applicable to that commodity or a category of commodities;

- (d) In reply to this request the importing Party explains the overall and individual objective and the rationale behind its measure(s), including the identification of the risk;
  - (e) With this explanation, the importing Party informs the exporting Party on the relationship of its domestic measures and the import conditions for that commodity;
  - (f) The exporting Party objectively demonstrates to the importing Party that the measures that it has identified are equivalent to the import conditions for that commodity or a category of commodities;
  - (g) The importing Party objectively assesses the demonstration of equivalence by the exporting Party;
  - (h) The importing Party concludes whether equivalence is achieved or not;
  - (i) The importing Party provides to the exporting Party full explanation and supporting data for its determination and decision if so required by the exporting Party;
4. Demonstration of equivalence of measures by the exporting party and assessment of this demonstration by the importing Party
- (a) The exporting Party shall objectively demonstrate equivalence for each of the identified measures of the importing Party expressed in its import conditions. When appropriate, equivalence shall objectively be demonstrated for any plan or program required by the importing Party as a condition to allow import (e.g. residue plan);

(b) Objective demonstration and assessment in this context should be based, as far as possible, on:

- internationally recognised standards; and/or standards based on proper scientific evidence; and/or
- risk assessment; and/or
- documents, reports and information related to past experiences, assessments and verifications; and
- legal status or level of administrative status of the measures; and
- level of implementation and enforcement on the basis of in particular:
  - corresponding and relevant results of surveillance and monitoring programmes;
  - inspection results of the exporting Party;
  - results of analysis with recognised analysis methods;
  - verification and import check results by the importing Party;
  - the performance of the competent authorities of the exporting Party; and
  - earlier experiences.

5. Conclusions of the importing Party

In case the importing Party arrives at a negative conclusion, it shall provide the exporting Party with a detailed and reasoned explanation.

6. For plants and plant products, equivalence concerning phytosanitary measures, shall be based on the conditions referred into Article 183(6) of this Agreement.

## **ANNEX XXII**

### **IMPORT CHECKS AND INSPECTION FEES**

#### **A. Principles of import checks**

Import checks consist of documentary checks, identity checks and physical checks

As regards animals and animal products, the physical checks and their frequency shall be based on the level of the risk associated with such imports.

In carrying out the checks for plant health purposes, the importing Party shall ensure that the plants, plant products and other objects shall be meticulously inspected on an official basis, either in their entirety or by inspecting a representative sample, in order to make sure, that they are not contaminated by pests.

In the event that the checks reveal non-conformity with the relevant standards and/or requirements, the importing Party shall take official measures proportionate to the risk involved. Wherever possible, the importer or his representative shall be given access to the consignment and the opportunity to provide any relevant information to assist the importing Party in taking a final decision concerning the consignment. Such decision shall be proportional to the level of the risk associated with such imports.

## B. Frequencies of physical checks

## B.1. Import of animals and animal products to the EU and the Republic of Moldova

| Type of frontier check                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Frequency rate |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 1. Documentary checks                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 100 %          |
| 2. Identity checks                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 100 %          |
| 3. Physical checks                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                |
| Live animals 100 %                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 100 %          |
| Category I products<br>Fresh meat including offal, and products of the bovine, ovine, caprine, porcine and equine species defined in Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marking of fresh meat, as amended.<br>Fish products in hermetically sealed containers intended to render them stable at ambient temperatures, fresh and frozen fish and dry and/or salted fisheries products<br>Whole eggs<br>Lard and rendered fats<br>Animal casings<br>Hatching eggs | 20 %           |

| Type of frontier check                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Frequency rate |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <p>Category II products</p> <p>Poultry meat and poultry meat products</p> <p>Rabbit meat, game meat (wild/farmed) and products thereof</p> <p>Milk and milk products for human consumption</p> <p>Egg products</p> <p>Processed animal protein for human consumption (100 % for the first six bulked consignments, Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, as amended).</p> <p>Other fish products than those mentioned under the Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted, as amended.</p> <p>Bivalve molluscs</p> <p>Honey</p> | 50 %           |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| <p>Category III products</p> <p>Semen</p> <p>Embryos</p> <p>Manure</p> <p>Milk and milk products (not for human consumption)</p> <p>Gelatine</p> <p>Frog's legs and snails</p> <p>Bones and bone products</p> <p>Hides and skins</p> <p>Bristles, wool, hair and feathers</p> <p>Horns, horn products, hooves and hoof products</p> <p>Apiculture products</p> <p>Game trophies</p> <p>Processed pet food</p> <p>Raw material for the manufacture of pet food</p> <p>Raw material, blood, blood products, glands and organs for pharmaceutical or technical use</p> <p>Hay and straw</p> <p>Pathogens</p> <p>Processed animal protein (packaged)</p> | <p>Minimum of 1 %</p> <p>Maximum of 10 %</p> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|

| Type of frontier check                                    | Frequency rate                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Processed animal protein not for human consumption (bulk) | 100 % for the first six consignments (points 10 and 11 of Chapter II of Annex VII to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 30 October 2002 laying down health rules concerning animal by-products not intended for human consumption, as amended). |

## B.2. Import of non-animal food to the EU and the Republic of Moldova

|                                                                                                                                                                                                                                                                                                       |                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| <ul style="list-style-type: none"> <li>— Chilli (<i>Capsicum annuum</i>), crushed or ground — ex 0904 20 90</li> <li>— Chilli products (curry) — 0910 91 05</li> <li>— <i>Curcuma longa</i> (turmeric) — 0910 30 00</li> <li>(Food — dried spices)</li> <li>— Red palm oil — ex 1511 10 90</li> </ul> | 10 % for Sudan dyes from all third countries |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|

### B.3. Import in to the EU and the Republic of Moldova of plants, plant products and other objects

For plants, plant products and other objects listed in Annex V, Part B to Directive 2000/29/EC:

The importing Party carries out checks in order to verify the phytosanitary status of the consignment(s).

A reduced frequency of plant health import checks could be set up for regulated commodities with the exception of plants, plant product and other objects defined accordingly to Commission Regulation (EC) No 1756/2004 of 11 October 2004 specifying the detailed conditions for the evidence and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V to Directive 2000/29/EC.

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## **ANNEX XXIII**

### **CERTIFICATION**

#### **A. Principles of certification**

Plants and plant products and other objects:

In respect of certification of plants and plant products and other objects, the competent authorities shall apply the principles laid down in the relevant ISPMs

Animals and animal products:

1. The competent authorities of the Parties shall ensure that certifying officers have a satisfactory knowledge of the veterinary law as regards the animals or animal products to be certified and, in general, are informed about the rules to be followed for drawing up and issuing of the certificates and, if necessary, as to the nature and extent of the enquiries, tests or examinations which should be carried out before certification.
2. Certifying officers must not certify data of which they have no personal knowledge or which cannot be ascertained by them.
3. Certifying officers must not sign blank or incomplete certificates, or certificates relating to animals or animal products, which they have not inspected or which have passed out of their control. Where a certificate is signed on the basis of another certificate or attestation, the certifying officer shall be in possession of the latter document before signing.

4. A certifying officer may certify data which have been:
  - (a) ascertained on the basis of paragraphs 1 to 3 of this Annex by another person authorised by the competent authority and acting under the control of the latter authority, provided that the certifying officer can verify the accuracy of the data; or
  - (b) obtained, in the context of monitoring programmes, by reference to officially recognized quality assurance schemes or by means of an epidemiological surveillance system where this is authorized under veterinary legislation.
5. The competent authorities of the Parties shall take all necessary steps to ensure the integrity of certification. In particular they shall ensure that certifying officers designated by them:
  - (a) have a status which ensures their impartiality and have no direct commercial interest in the animals or products being certified or in the holdings or establishments in which they originate; and
  - (b) are fully aware of the significance of the contents of each certificate which they sign.
6. Certificates shall be drawn up in order to ensure that a specific certificate refers to a specific consignment in a language understood by the certifying officer and in at least one of the official languages of the importing Party as set out in part C of this Annex.

The date of signature of the certificate cannot be after the date of dispatch of the consignment(s).

7. Each competent authority shall be in a position to link a certificate with the relevant certifying officer and ensure that a copy of all certificates issued is available for a period to be determined by that competent authority.
8. Each Party shall introduce the checks and the controls necessary to prevent the issuing of false or misleading certifications and the fraudulent production or use of certificates purported to be issued for the purpose set out in the veterinary law.
9. Without prejudice to any judicial proceedings or penalties, the competent authorities shall carry out investigations or checks and take appropriate measures to penalise any instances of false or misleading certification, which are brought to their attention. Such measures may include the temporary suspension of the certifying officers from their duties until the investigation is over. In particular:
  - (a) if in the course of the checks it is found that a certifying officer has knowingly issued a fraudulent certificate, the competent authority shall take all necessary steps to ensure, as far as is possible, that the person concerned cannot repeat the offence;
  - (b) if in the course of the checks it is found that an individual or an undertaking has made fraudulent use of or has altered an official certificate, the competent authority shall take all necessary measures to ensure, as far as possible, that the individual or the undertaking cannot repeat the offence. Such measures may include a refusal to issue an official certificate to the person or the undertaking concerned.

B. Certificate referred to in Article 186(2)(a) of this Agreement

The health attestation in the certificate reflects the status of equivalence of the commodity concerned. The health attestation states compliance with the production standards of the exporting Party recognised equivalent by the importing Party.

C. Official languages for certification

1. Import into the EU. Plants, plant products and other objects:

Certificates shall be drawn up in a language understood by the certifying officer and in at least one of the official languages of the importing Party.

Animals and animal products:

The health certificate must be drawn up in at least one of the official languages of the Member State of destination and in one of those of the Member State in which the import checks provided for in Article 189 of this Agreement are carried out.

2. Import into Republic of Moldova

The health certificate must be drawn up in the official language of the Republic of Moldova.

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## **ANNEX XXIV**

### **APPROXIMATION**

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**ANNEX XXIV-A****PRINCIPLES FOR THE EVALUATION OF PROGRESS IN THE APPROXIMATION  
PROCESS****Part I****Gradual approximation****1. General rules**

The sanitary, phytosanitary and animal welfare law of the Republic of Moldova shall be gradually approximated to that of the Union, based on the approximation list of the EU sanitary, phytosanitary and animal welfare law. The list shall be divided into priority areas that relate to measures, as defined in Annex XVII to this Agreement which will be based on the technical and financial resources of the Republic of Moldova. For this reason the Republic of Moldova shall identify its trade priority areas.

The Republic of Moldova shall approximate its domestic rules by either:

- (a) implementing and enforcing through the adoption of additional domestic rules or procedures the rules in pertinent basic EU *acquis*; or
- (b) by amending relevant domestic rules or procedures to incorporate the rules in relevant basic EU *acquis*.

In either case, the Republic of Moldova shall:

- (a) eliminate any domestic laws, regulations, practices or other measures inconsistent with the approximated domestic rules; and
- (b) ensure the effective implementation of approximated domestic rules.

The Republic of Moldova shall document such approximation in tables of correspondence according to a model indicating the date on which domestic rules enter into force and the official journal in which the rules were published. The model of the tables of correspondence for the preparation and the evaluation is provided in Part II of this Annex. If the approximation is not complete, reviewers<sup>1</sup> shall describe the shortcomings in the column provided for comments.

Irrespective of the priority area identified, the Republic of Moldova shall prepare specific tables of correspondence demonstrating the approximation for other general and specific legislation including in particular the general rules related to:

- (a) Control systems
  - domestic market;
  - imports.
- (b) Animal health and welfare
  - the identification and the registration of animals and the registration of their movements;

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<sup>1</sup> Reviewers shall be experts appointed by European Commission.

- the control measures for animal diseases;
- domestic trade with live animals, semen, ova and embryos;
- animal welfare on farms, during transport and slaughter.

(c) Food safety

- placing on the market of food and feed;
- labelling, presentation and advertising of food including nutritional and health claims;
- residues controls;
- specific rules for feed.

(d) Animal by-products

(e) Plant health

- harmful organisms;
- plant protection products;

(f) Genetically modified organisms:

- released into the environment;
- genetically modified food and feed.

## **Part II**

### **Evaluation**

#### **1. Procedure and method:**

The Republic of Moldova's sanitary, phytosanitary and animal welfare law covered by Chapter 4 of Title V (Trade and Trade-related Matters) shall be gradually approximated by the Republic of Moldova to that of the Union and shall be effectively enforced<sup>1</sup>.

Tables of correspondence shall be prepared according to the model as laid down in point 2 for each single approximated act and submitted in English for review by the reviewers.

If the result of the evaluation is positive for an individual measure, a group of measures, a system applicable to a sector, sub-sector, a commodity or a group of commodities, the conditions of Article 183(4) of this Agreement shall apply.

#### **2. Tables of correspondence**

##### **2.1. When preparing tables of correspondence, the following shall be taken into consideration:**

The Union acts shall serve as a basis for preparation of a table of correspondence. To this end the version in force at the time of approximation shall be used. The Republic of Moldova shall pay particular attention to precise translation into the national language, as linguistic imprecision can give rise to disputes in particular if they concern the scope of the law<sup>2</sup>.

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<sup>1</sup> For this occasion, it may be supported by the Member States' experts separately or in the margin of the CIB programs (twinning projects, TAIEX etc.).

<sup>2</sup> To facilitate the approximation process, consolidated versions of certain pieces of EU legislation are available at the EUR-lex web page under:  
<http://eur-lex.europa.eu/homepage.html>

## 2.2. Model of table of correspondence:

TABLE OF CORRESPONDENCE  
BETWEEN  
Title of the EU act, latest amendments incorporated:  
AND  
Title of the national text  
(Published in )

Date of publication:

Date of implementation:

| EU Act | National legislation | Remarks (from the Republic of Moldova) | Reviewer's comments |
|--------|----------------------|----------------------------------------|---------------------|
|        |                      |                                        |                     |

Legend:

**EU Act:** its articles, paragraphs, sub-paragraphs etc. shall be mentioned with full title and reference<sup>1</sup> in the left column of the table of correspondence.

**National legislation:** the provisions of the national legislation corresponding to the EU provisions of the left column shall be mentioned with their full title and reference. Their content shall be described in the second column in detail.

**Remarks from the Republic of Moldova:** in this column the Republic of Moldova shall indicate the reference or other provisions associated with this article, paragraphs, sub-paragraphs etc. especially when the text of the provision is not approximated. The relevant reason for absence of approximation shall be explained.

**Reviewer's comments:** in case reviewers consider that approximation is not achieved, they shall justify this evaluation and describe relevant shortcomings in this column.

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<sup>1</sup> i.e. as indicated on the EUR-lex web page: <http://eur-lex.europa.eu/homepage.html>

## **ANNEX XXIV-B**

### **LIST OF THE EU LEGISLATION TO BE APPROXIMATED TO BY THE REPUBLIC OF MOLDOVA**

The approximation list referred to in Article 181(4) of this Agreement will be submitted by the Republic of Moldova within three months after the entry into force of this Agreement.

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## **ANNEX XXV**

### **STATUS OF EQUIVALENCE**

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**ANNEX XXVI****APPROXIMATION OF CUSTOMS LEGISLATION****Customs Code**

Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code

Timetable: The approximation with the provisions of the above mentioned Regulation shall be carried out by the Republic of Moldova within three years following the entry into force of this Agreement

**Common Transit and SAD**

Convention of 20 May 1987 on the simplification of formalities in trade in goods

Convention of 20 May 1987 on a common transit procedure

Timetable: The approximation with the provisions of those Conventions shall be carried out by the Republic of Moldova within three years following the entry into force of this Agreement

**Reliefs from customs duty**

Council Regulation (EC) No 1186/2009 of 16 November 2009 setting up a Community system of reliefs from customs duty

Timetable: The approximation with Titles I and II of this Regulation shall be carried out by the Republic of Moldova within three years following the entry into force of this Agreement.

**IPR protection**

Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights

Timetable: The approximation with the provisions of that Regulation shall be carried out by the Republic of Moldova within one year following the entry into force of this Agreement.

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