



Brussels, 18.4.2016  
COM(2016) 211 final

ANNEX 1

**ANNEX**

**to the**

**Proposal for a Council Decision**

**on the position to be adopted, on behalf of the European Union, in the Sanitary and Phytosanitary Sub-Committee established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other**

**ATTACHMENT**

**DRAFT**

**DECISION NO 1/2016 OF THE EU-REPUBLIC OF MOLDOVA SANITARY AND  
PHYTOSANITARY SUB-COMMITTEE**

**of ...2016**

**modifying Annex XXIV-B to the Association Agreement**

THE SANITARY AND PHYTOSANITARY SUB-COMMITTEE,

Having regard to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part, signed in Brussels on 27 June 2014, and in particular Article 181 and Article 191 thereof,

Whereas:

- (1) In accordance with Article 464 of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States of the one part, and the Republic of Moldova, of the other part ('the Agreement'), parts of the Agreement, including the provisions on sanitary and phytosanitary measures, are applied provisionally as of 1 September 2014.
- (2) Article 181(1) of the Agreement provides that the Republic of Moldova shall gradually approximate its sanitary and phytosanitary and animal welfare law to that of the Union as set out in Annex XXIV to that Agreement.
- (3) Article 181(4) of the Agreement commits the Republic of Moldova to submit a list of Union sanitary, phytosanitary and animal welfare *acquis* to which it intends to approximate its domestic legislation, no later than three months after the entry into force of the Agreement. That list is to serve as a reference document for the implementation of Chapter 4 of Title V (Trade and trade-related matters) of the Agreement.
- (4) Article 191 of the Agreement established the Sanitary and Phytosanitary Sub-Committee, which is to consider any matter related to Chapter 4 of Title V (Trade and trade-related matters), including its implementation, and may review and modify Annex XXIV to the Agreement.
- (5) The Republic of Moldova submitted the above-mentioned list of the Union *acquis* to the European Commission in November 2014, following which, in consultation with the European Commission, the list was finalised in July 2015.
- (6) It is appropriate that the Sanitary and Phytosanitary Sub-Committee takes a decision to amend Annex XXIV-B to the Agreement to include the list as set out in the Annex to this Decision,

HAS ADOPTED THIS DECISION:

*Article 1*

Annex XXIV-B to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States of the one part, and the Republic of Moldova, of the other part, is hereby modified as set out in the Annex to this Decision.

*Article 2*

This Decision shall enter into force on the day of its adoption.

Done at ..., ...

*For the Sanitary and Phytosanitary Sub-Committee*

*The Chair*

**MODIFICATION OF ANNEX XXIV-B TO THE ASSOCIATION AGREEMENT**

Annex XXIV-B to the Agreement is hereby modified and shall read as follows:

“ANNEX XXIV-B

**LIST OF THE UNION LEGISLATION TO BE APPROXIMATED TO BY THE REPUBLIC OF MOLDOVA**

In accordance with Article 181(4) of this Agreement, the Republic of Moldova shall approximate its legislation to the following Union legislation within the timeframes as listed below.

<b>Union legislation</b>	<b>Deadline for approximation</b>
<b>Section 1 – General</b>	
Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, with the exception of Articles 58, 59 and 62	2016
Commission Regulation (EC) No 1304/2003 of 23 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it	2020
Commission Decision 2004/478/EC of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management	2016
Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed	2016
Commission Regulation (EC) No 1151/2009 of 27 November 2009 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil and repealing Decision 2008/433/EC	2019
Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009	2018
Commission Regulation (EU) No 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352/EC	2019

Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts	2019
Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin	2018
Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety – Articles 58, 59 and 62	2018
<b>Section 2 – Veterinary</b>	
Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption	2017
Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerized veterinary system	2019
Commission Decision 2005/734/EC of 19 October 2005 laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk	2018
Commission Decision 2006/415/EC of 14 June 2006 concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in the Community and repealing Decision 2006/135/EC	2018
Commission Decision 2006/563/EC of 11 August 2006 concerning certain protection measures in relation to highly pathogenic avian influenza of subtype H5N1 in wild birds in the Community and repealing Decision 2006/115/EC	2018
Commission Decision 2010/57/EU of 3 February 2010 laying down health guarantees for the transit of equidae being transported through the territories listed in Annex I to Council Directive 97/78/EC	2018
Commission Implementing Regulation (EU) No 139/2013 of 7 January 2013 laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof	2017
Commission Implementing Regulation (EU) No 750/2014 of 10 July 2014 on protection measures in relation to porcine epidemic diarrhoea as regards the animal health requirements for the introduction into the Union of porcine animals	2019
Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organization of veterinary checks on products entering the	2017

Community from third countries	
Commission Decision 78/685/EEC of 26 July 1978 establishing a list of epizootic diseases in accordance with Directive 72/462/EEC	2015
Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine	2019
Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals	2019
Commission Decision 2006/968/EC of 15 December 2006 implementing Council Regulation (EC) No 21/2004 as regards guidelines and procedures for the electronic identification of ovine and caprine animals	2019
Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae	2019
Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae	2017
Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever	2017
Commission Decision 2002/106/EC of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever	2017
Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever	2017
Commission Decision 2003/422/EC of 26 May 2003 approving an African swine fever diagnostic manual	2017
Commission Decision 2006/437/EC of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC	2017
Commission Regulation (EC) No 616/2009 of 13 July 2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments	2017
Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease	2018
Council Directive 2000/75/EC of 20 November 2000 laying down specific	2018

provisions for the control and eradication of bluetongue	
Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue	2018
Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies	2016
Commission Decision 2007/843/EC of 11 December 2007 concerning approval of <i>Salmonella</i> control programmes in breeding flocks of <i>Gallus gallus</i> in certain third countries in accordance with Regulation (EC) No 2160/2003 of the European Parliament and of the Council and amending Decision 2006/696/EC, as regards certain public health requirements at import of poultry and hatching eggs	2015
Commission Decision 2007/848/EC of 11 December 2007 approving certain national programmes for the control of salmonella in flocks of laying hens of <i>Gallus gallus</i>	2015
Commission Decision 2008/815/EC of 20 October 2008 approving certain national programmes for the control of Salmonella in flocks of broilers of <i>Gallus gallus</i>	2015
Commission Decision 2009/771/EC of 20 October 2009 approving certain national programmes for the control of salmonella in turkeys	2015
Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease	2017
Commission Decision 2004/226/EC of 4 March 2004 approving tests for the detection of antibodies against bovine brucellosis within the framework of Council Directive 64/432/EEC	2019
Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals	2019
Commission Decision 95/329/EC of 25 July 1995 defining the categories of male equidae to which the requirement regarding viral arteritis laid down in Article 15 (b) (ii) of Council Directive 90/426/EEC applies	2019
Commission Decision 2001/183/EC of 22 February 2001 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC	2019
Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species	2020

Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC	2019
Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC	2017
Council Decision 1999/879/EC of 17 December 1999 concerning the placing on the market and administration of bovine somatotrophin (BST) and repealing Decision 90/218/EEC	2016
Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products	2016
Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products	2016
Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals	2018
Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results	2016
Commission Decision 92/260/EEC of 10 April 1992 on animal health conditions and veterinary certification for temporary admission of registered horses	2017
Commission Decision 2008/946/EC of 12 December 2008 implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals	2019
Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC	2018
Commission Decision 2006/778/EC of 14 November 2006 concerning minimum requirements for the collection of information during the inspections of production sites on which certain animals are kept for farming purposes	2019
Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves	2018



Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs	2018
Commission Implementing Decision 2013/188/EU of 18 April 2013 on annual reports on non-discriminatory inspections carried out pursuant to Council Regulation (EC) No 1/2005 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97	2018
Council Regulation (EC) No 1255/97 of 25 June 1997 concerning Community criteria for control posts and amending the route plan referred to in the Annex to Directive 91/628/EEC	2019
Council Directive 2009/157/EC of 30 November 2009 on pure-bred breeding animals of the bovine species	2016
Commission Decision 84/247/EEC of 27 April 1984 laying down the criteria for the recognition of breeders' organizations and associations which maintain or establish herd-books for pure-bred breeding animals of the bovine species	2019
Commission Decision 84/419/EEC of 19 July 1984 laying down the criteria for entering cattle in herd-books	2017
Council Directive 87/328/EEC of 18 June 1987 on the acceptance for breeding purposes of pure-bred breeding animals of the bovine species	2016
Council Decision 96/463/EC of 23 July 1996 designating the reference body responsible for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species	2019
Commission Decision 2005/379/EC of 17 May 2005 on pedigree certificates and particulars for pure-bred breeding animals of the bovine species, their semen, ova and embryos	2019
Commission Decision 2006/427/EC of 20 June 2006 laying down performance monitoring methods and methods for assessing cattle's genetic value for pure-bred breeding animals of the bovine species	2019
Council Directive 88/661/EEC of 19 December 1988 on the zootechnical standards applicable to breeding animals of the porcine species	2016
Commission Decision 89/501/EEC of 18 July 1989 laying down the criteria for approval and supervision of breeders' associations and breeding organizations which establish or maintain herd-books for pure-bred breeding pigs	2019
Commission Decision 89/502/EEC of 18 July 1989 laying down the criteria governing entry in herd-books for pure-bred breeding pigs	2017
Commission Decision 89/503/EEC of 18 July 1989 laying down the certificate of pure-bred breeding pigs, their semen, ova and embryos	2017
Commission Decision 89/504/EEC of 18 July 1989 laying down the criteria for	2016

approval and supervision of breeders' associations, breeding organizations and private undertakings which establish or maintain registers for hybrid breeding pigs	
Commission Decision 89/505/EEC of 18 July 1989 laying down the criteria governing entry in registers for hybrid breeding pigs	2019
Commission Decision 89/506/EEC of 18 July 1989 laying down the certificate of hybrid breeding pigs, their semen, ova and embryos	2019
Commission Decision 89/507/EEC of 18 July 1989 laying down methods for monitoring performance and assessing the genetic value of pure-bred and hybrid breeding pigs	2019
Council Directive 90/118/EEC of 5 March 1990 on the acceptance of pure-bred breeding pigs for breeding	2016
Council Directive 90/119/EEC of 5 March 1990 of hybrid breeding pigs for breeding	2016
Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats	2016
Commission Decision 90/254/EEC of 10 May 1990 laying down the criteria for approval of breeders' organizations and associations which establish or maintain flock-books for pure-bred breeding sheep and goats	2019
Commission Decision 90/255/EEC of 10 May 1990 laying down the criteria governing entry in flock-books for pure-bred breeding sheep and goats	2019
Commission Decision 90/258/EEC of 10 May 1990 laying down the zootechnical certificates for pure-bred breeding sheep and goats, their semen, ova and embryos	2016
Commission Decision 92/353/EEC of 11 June 1992 laying down the criteria for the approval or recognition of organizations and associations which maintain or establish stud-books for registered equidae	2019
Commission Decision 92/354/EEC of 11 June 1992 laying down certain rules to ensure coordination between organizations and associations which maintain or establish stud-books for registered equidae	2019
Commission Decision 96/78/EC of 10 January 1996 laying down the criteria for entry and registration of equidae in stud-books for breeding purposes	2017
Commission Decision 96/79/EC of 12 January 1996 laying down the zootechnical certificates of semen, ova and embryos from registered equidae	2017
Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae	2017

Council Directive 90/428/EEC of 26 June 1990 on trade in equidae intended for competitions and laying down the conditions for participation therein	2018
Commission Decision 92/216/EEC of 26 March 1992 on the collection of data concerning competitions for equidae as referred to in Article 4 (2) of Council Directive 90/428/EEC	2018
Council Directive 91/174/EEC of 25 March 1991 laying down zootechnical and pedigree requirements for the marketing of pure-bred animals and amending Directives 77/504/EEC and 90/425/EEC	2016
<b>Section 3 – Placing on the market of food, feed and animal by-products</b>	
Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs	2017
Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin	2017
Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004	2017
Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts	2018
Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council	2018
Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts	2018
Commission Regulation (EU) No 579/2014 of 28 May 2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea	2018
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	2018
Commission Regulation (EU) No 101/2013 of 4 February 2013 concerning the	2016

use of lactic acid to reduce microbiological surface contamination on bovine carcasses	
Commission Implementing Regulation (EU) No 636/2014 of 13 June 2014 on a model certificate for the trade of unskinned large wild game	2018
Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules	2017
Commission Decision 2007/363/EC of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council	2017
Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed	2017
Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC	2017
Commission Decision 2008/654/EC of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council	2017
Commission Implementing Regulation (EU) No 702/2013 of 22 July 2013 on transitional measures for the application of Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the accreditation of official laboratories carrying out official testing for Trichinella and amending Commission Regulation (EC) No 1162/2009	2017
Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption	2017
Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC	2017
Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and	2016

Regulation (EC) No 726/2004 of the European Parliament and of the Council	
Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat	2017
Council Decision 92/608/EEC of 14 November 1992 laying down methods for the analysis and testing of heat-treated milk for direct human consumption	2017
Commission Decision 2002/226/EC of 15 March 2002 establishing special health checks for the harvesting and processing of certain bivalve molluscs with a level of amnesic shellfish poison (ASP) exceeding the limit laid down by Council Directive 91/492/EEC	2018
Commission Implementing Regulation (EU) No 702/2013 of 22 July 2013 on transitional measures for the application of Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the accreditation of official laboratories carrying out official testing for Trichinella and amending Commission Regulation (EC) No 1162/2009	2017
Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002	2017
Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive	2017
Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules	2017
Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene	2017
Commission Regulation (EC) No 141/2007 of 14 February 2007 concerning a requirement for approval in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council for feed business establishments manufacturing or placing on the market feed additives of the category coccidiostats and histomonostats	2019
<b>Section 4 – Food Safety Rules</b>	
Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the	2017

Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004	
Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods	2016
Directive 2011/91/EU of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs	2018
Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health	2017
Commission Regulation (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims	2016
Commission Implementing Decision 2013/63/EU of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council	2016
Commission Regulation (EU) No 851/2013 of 3 September 2013 authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012	2017
Commission Regulation (EU) No 40/2014 of 17 January 2014 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012	2017
Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods	2017
Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements	2017
Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings	2017
Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings	2017
Regulation (EC) No 1332/2008 of the European Parliament and of the Council	2016

of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97	
Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients	2019
Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs – Article 1, Article 2, Article 3(1) and (2), as provided for in Article 6(2) of Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012	2017
Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods	2017
Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC	2017
Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC	2017
Commission Regulation (EU) No 873/2012 of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council	2017
Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings	2017
Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs	2016
Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food	2016
Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs	2015

Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs	2017
Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs	2017
Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers	2017
Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food	2017
Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food	2018
Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China	2016
Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles	2016
Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006	2015
Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements	2016
Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009	2016
Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC	2016
Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten	2018
Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular	2018



nutritional uses	
Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption	2018
Commission Regulation (EC) No 37/2005 of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quickfrozen foodstuffs intended for human consumption	2018
Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food	2016
Commission Recommendation 2006/794/EC of 16 November 2006 on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs	2018
Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs	2016
Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs	2016
Commission Recommendation 2011/516/EU of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food	2018
Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012	2018
Commission Recommendation 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products	2018
Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients	2017
Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation	2019
Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation	2019
Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters	2018
Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural	2018

mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters	
Commission Regulation (EU) No 115/2010 of 9 February 2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters	2018
<b>Section 5 – Specific Rules for Feed</b>	
Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC	2017
Commission Directive 82/475/EEC of 23 June 1982 laying down the categories of feed materials which may be used for the purposes of labelling compound feeding stuffs for pet animals	2019
Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes (Codified version)	2019
Commission Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products	2019
Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials	2019
Commission Regulation (EC) No 1876/2006 of 18 December 2006 concerning the provisional and permanent authorisation of certain additives in feedingstuffs	2019
Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives	2019
Commission Regulation (EU) No 1270/2009 of 21 December 2009 concerning the permanent authorisations of certain additives in feedingstuffs	2019
Commission Regulation (EU) No 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council	2019
Commission Recommendation 2004/704/EC of 11 October 2004 on the monitoring of background levels of dioxins and dioxin-like PCBs in feedingstuffs	2019
<b>Section 6 – Phytosanitary</b>	
Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant	2020

products and against their spread within the Community	
Commission Regulation (EC) No 1756/2004 of 11 October 2004 specifying the detailed conditions for the evidence required 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 Council Directive 2000/29/EC	2018
Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks	2018
Commission Implementing Directive 2014/78/EU of 17 June 2014 amending Annexes I, II, III, IV and V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community	2017
Commission Implementing Directive 2014/83/EU of 25 June 2014 amending Annexes I, II, III, IV and V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community	2017
Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers	2016
Commission Implementing Decision 2014/497/EU of 23 July 2014 as regards measures to prevent the introduction into and the spread within the Union of <i>Xylella fastidiosa</i> (Well and Raju)	2016
Commission Decision 2002/757/EC of 19 September 2002 on provisional emergency phytosanitary measures to prevent the introduction into and the spread within the Community of <i>Phytophthora ramorum</i> Werres, De Cock & Man in 't Veld sp. nov.	2016
Commission Decision 2006/464/EC of 27 June 2006 on provisional emergency measures to prevent the introduction into and the spread within the Community of <i>Dryocosmus kuriphilus</i> Yasumatsu	2019
Commission Decision 2003/766/EC of 24 October 2003 on emergency measures to prevent the spread within the Community of <i>Diabrotica virgifera</i> Le Conte	2017
Commission Implementing Directive 2014/19/EU of 6 February 2014 amending Annex I to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community	2017
Commission Implementing Decision (EU) 2015/749 of 7 May 2015 repealing Decision 2007/410/EC on measures to prevent the introduction into and the spread within the Community of Potato spindle tuber viroid	2017

Commission Decision 2008/840/EC of 7 November 2008 on emergency measures to prevent the introduction into and the spread within the Community of <i>Anoplophora chinensis</i> (Forster)	2018
Commission Implementing Decision 2012/270/EU of 16 May 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of <i>Epitrix cucumeris</i> (Harris), <i>Epitrix similaris</i> (Gentner), <i>Epitrix subcrinita</i> (Lec.) and <i>Epitrix tuberis</i> (Gentner)	2016
Commission Decision 2006/133/EC of 13 February 2006 requiring Member States temporarily to take additional measures against the dissemination of <i>Bursaphelenchus xylophilus</i> (Steiner et Buhrer) Nickle <i>et al.</i> (the pine wood nematode) as regards areas in Portugal, other than those in which it is known not to occur	2017
Commission Implementing Decision 2012/535/EU of 26 September 2012 on emergency measures to prevent the spread within the Union of <i>Bursaphelenchus xylophilus</i> (Steiner et Buhrer) Nickle <i>et al.</i> (the pine wood nematode)	2018
Commission Implementing Decision 2012/138/EU of 1 March 2012 as regards emergency measures to prevent the introduction into and the spread within the Union of <i>Anoplophora chinensis</i> (Forster)	2018
Commission Regulation (EC) No 690/2008 of 4 July 2008 recognising protected zones exposed to particular plant health risks in the Community	2019
Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register	2018
Commission Decision 2004/416/EC of 29 April 2004 on emergency measures in respect of certain citrus fruits originating in Brazil	2020
Commission Decision 2006/473/EC of 5 July 2006 recognising certain third countries and certain areas of third countries as being free from <i>Xanthomonas campestris</i> (all strains pathogenic to Citrus), <i>Cercospora angolensis</i> Carv. et Mendes and <i>Guignardia citricarpa</i> Kiely (all strains pathogenic to Citrus)	2020
Commission Implementing Decision 2012/756/EU of 5 December 2012 as regards measures to prevent the introduction into and the spread within the Union of <i>Pseudomonas syringae</i> pv. <i>actinidiae</i> Takikawa, Serizawa, Ichikawa, Tsuyumu & Goto	2020
Commission Implementing Decision 2013/92/EU of 18 February 2013 on the supervision, plant health checks and measures to be taken on wood packaging material actually in use in the transport of specified commodities originating in China	2018
Commission Implementing Decision 2014/237/EU of 24 April 2014 on measures to prevent the introduction into and the spread within the Union of	2019

harmful organisms as regards certain fruits and vegetables originating in India	
Commission Implementing Decision 2014/422/EU of 2 July 2014 setting out measures in respect of certain citrus fruits originating in South Africa to prevent the introduction into and the spread within the Union of <i>Phyllosticta citricarpa</i> (McAlpine) Van der Aa	2020
Commission Directive 98/22/EC of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries	2016
Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections (Codified version)	2016
Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC	2020
Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances	2019
Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances	2019
Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products	2019
Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products	2019
Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products	2019
Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides	2019
Council Decision 2005/834/EC of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries and amending Decision 2003/17/EC	2019
Commission Directive 2004/29/EC of 4 March 2004 on determining the	2018

characteristics and minimum conditions for inspecting vine varieties	
Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material	2018
Commission Regulation (EC) No 1597/2002 of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the format of national lists of the basic material of forest reproductive material	2019
Commission Regulation (EC) No 2301/2002 of 20 December 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the definition of small quantities of seed	2019
Commission Regulation (EC) No 69/2004 of 15 January 2004 authorising derogations from certain provisions of Council Directive 1999/105/EC in respect of the marketing of forest reproductive material derived from certain basic material	2019
Council Decision 2008/971/EC of 16 December 2008 on the equivalence of forest reproductive material produced in third countries	2018
Commission Decision 2008/989/EC of 23 December 2008 authorising Member States, in accordance with Council Directive 1999/105/EC, to take decisions on the equivalence of the guarantees afforded by forest reproductive material to be imported from certain third countries	2018
Commission Recommendation 2012/90/EU of 14 February 2012 on guidelines for the presentation of the information for the identification of lots of forest reproductive material and the information to be provided on the supplier's label or document	2018
Commission Directive 2003/91/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/55/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of vegetable species	2017
Commission Implementing Directive 2014/20/EU of 6 February 2014 determining Union grades of basic and certified seed potatoes, and the conditions and designations applicable to such grades	2017
Commission Implementing Directive 2014/21/EU of 6 February 2014 determining minimum conditions and Union grades for pre-basic seed potatoes	2017
Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties	2019
Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened	2019

by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties	
<b>Section 7 – Genetically Modified Organisms</b>	
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 and repealing Council Directive 90/220/EEC	As specified in Annex XVI
Council Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC	2017
Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products	2017
Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms	2017
Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed	2018
Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation	2018
Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC	2018
Commission Recommendation 2010/C 200/01 of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops	2018
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 (Recast)	As specified in Annex XVI
Commission Decision No 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council	2018
<b>Section 8 – Veterinary medical products</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	As specified in Annex XVI
Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products	2019
Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin	2018
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	As specified in Annex XVI
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 authorizations for products for human or veterinary use	As specified in Annex XVI
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 (Codified version)	As specified in Annex XVI

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