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([1]) Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Legislative acts)

DIRECTIVES

DIRECTIVE 2010/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 7 July 2010

on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having consulted the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) The increase in the volume of road transport in the Union associated with the growth of the European economy and mobility requirements of citizens is the primary cause of increasing congestion of road infrastructure and rising energy consumption, as well as a source of environmental and social problems.

(2) The response to those major challenges cannot be limited to traditional measures, inter alia the expansion of the existing road transport infrastructure. Innovation will have a major role to play in finding appropriate solutions for the Union.

(3) Intelligent Transport Systems (ITS) are advanced applications which without embodying intelligence as such aim to provide innovative services relating to different modes of transport and traffic management and enable various users to be better informed and make safer, more coordinated and 'smarter' use of transport networks.

(4) ITS integrate telecommunications, electronics and information technologies with transport engineering in order to plan, design, operate, maintain and manage transport systems. The application of information and communication technologies to the road transport sector and its interfaces with other modes of transport will make a significant contribution to improving environmental performance, efficiency, including energy efficiency, safety and security of road transport, including the transport of dangerous goods, public security and passenger and freight mobility, whilst at the same time ensuring the functioning of the internal market as well as increased levels of competitiveness and employment. However, ITS applications should be without prejudice to matters concerning national security or which are necessary in the interest of defence.

(5) Advances in the field of the application of information and communication technologies to other modes of transport should now be reflected in developments in the road transport sector, in particular with a view to ensuring higher levels of integration between road transport and other modes of transport.

(6) In some Member States national applications of these technologies are already being deployed in the road transport sector. However, such deployment remains fragmented and uncoordinated and cannot provide geographical continuity of ITS services throughout the Union and at its external borders.

[1] OJ C 277, 17.11.2009, p. 85.

[2] Position of the European Parliament of 23 April 2009 (not yet published in the Official Journal), position of the Council of 10 May 2010 (not yet published in the Official Journal), position of the European Parliament of 6 July 2010 (not yet published in the Official Journal).

(7) To ensure a coordinated and effective deployment of ITS within the Union as a whole, specifications, including, where appropriate, standards, defining further detailed provisions and procedures should be introduced. Before adopting any specifications, the Commission should assess their compliance with certain defined principles set out in Annex II. Priority should be given in the first instance to the four main areas of ITS development and deployment. Within those four areas, priority actions should be established for the development and use of specifications and standards. During further implementation of ITS the existing ITS infrastructure deployed by a particular Member State should be taken into account in terms of technological progress and financial efforts made.

(8) When a legislative act is adopted as referred to in the second subparagraph of Article 6(2) of this Directive, the second sentence of Article 5(1) should be amended accordingly.

(9) The specifications should, inter alia take into account and build upon the experience and results already obtained in the field of ITS, notably in the context of the eSafety initiative, launched by the Commission in April 2002. The eSafety Forum was established by the Commission under that initiative to promote and further implement recommendations to support the development, deployment and use of eSafety systems.

(10) Vehicles which are operated mainly for their historical interest and were originally registered and/or type-approved and/or put into service before the entry into force of this Directive and of its implementing measures should not be affected by the rules and procedures laid down in this Directive.

(11) ITS should build on interoperable systems which are based on open and public standards and available on a non-discriminatory basis to all application and service suppliers and users.

(12) The deployment and use of ITS applications and services will entail the processing of personal data. Such processing should be carried out in accordance with Union law, as set out, in particular, in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] and in Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector [2], inter alia, the principles of purpose limitation and data minimisation should be applied to ITS applications.

(13) Anonymisation as one of the principles of enhancing individuals' privacy should be encouraged. As far as data protection and privacy related issues in the field of ITS applications and services deployment are concerned, the Commission should, as appropriate, further consult the European Data Protection Supervisor and request an opinion of the Working Party on the Protection of Individuals with regard to the Processing of Personal Data established by Article 29 of Directive 95/46/EC.

(14) The deployment and use of ITS applications and services, and notably traffic and travel information services, will entail the processing and use of road, traffic and travel data forming part of documents held by public sector bodies of the Member States. Such processing and use should be carried out in accordance with Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the re-use of public sector information [3].

(15) In appropriate cases, the specifications should include detailed provisions laying down the procedure governing assessment of conformity or suitability for use of constituents. Those provisions should be based on 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 [4], in particular concerning the modules for the various phases of the conformity assessment procedures. Directive 2007/46/EC of the European Parliament and of the Council [5] already establishes a framework for the type approval of motor vehicles and their parts or related equipment, and Directive 2002/24/EC of the European Parliament and of the Council [6] and Directive 2003/37/EC of the European Parliament and of the Council [7] lay down rules on the type approval of two or three-wheel motor vehicles, and agricultural or forestry tractors and their parts or related equipment. Therefore, it would be a duplication of work to provide for conformity assessment of equipment and applications falling within the scope of those Directives. At the same time, although those Directives apply to ITS-related equipment installed in vehicles, they do not apply to external road infrastructure ITS equipment and software. In such cases, the specifications could provide for conformity assessment procedures. Such procedures should be limited to what would be necessary in each separate case.

[1] OJ L 281, 23.11.1995, p. 31.

[2] OJ L 201, 31.7.2002, p. 37.
[3] OJ L 345, 31.12.2003, p. 90.
[4] OJ L 218, 13.8.2008, p. 82.
[5] OJ L 263, 9.10.2007, p. 1.
[6] OJ L 124, 9.5.2002, p. 1.
[7] OJ L 171, 9.7.2003, p. 1.

(16) For ITS applications and services for which accurate and guaranteed timing and positioning services are required, satellite-based infrastructures or any technology providing an equivalent level of precisions should be used, such as those provided for in Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations ([1]) and Regulation (EC) No 683/2008 of the European Parliament and of the Council of 9 July 2008 on the further implementation of the European satellite navigation programmes (EGNOS and Galileo) ([2]).

(17) Innovative technologies such as Radio Frequency Identification Devices (RFID) or EGNOS/Galileo should be used for the realisation of ITS applications, notably for the tracking and tracing of freight along its journey and across modes of transport.

(18) Major stakeholders such as ITS service providers, associations of ITS users, transport and facilities operators, representatives of the manufacturing industry, social partners, professional associations and local authorities should have the possibility to advise the Commission on the commercial and technical aspects of the deployment of ITS within the Union. For this purpose the Commission, ensuring close cooperation with stakeholders and Member States, should set up an ITS advisory group. The work of the advisory group should be carried out in a transparent manner and the result should be made available to the Committee established by this Directive.

(19) Uniform conditions of implementation should be ensured for the adoption of guidelines and non-binding measures to facilitate Member States cooperation in respect of priority areas on ITS as well as in respect of guidelines for reporting by the Member States and of a working programme.

(20) According to Article 291 of the Treaty on the Functioning of the European Union (TFEU), rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers shall be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([3]) continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(21) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the TFEU in respect of the adoption of specifications. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(22) In order to guarantee a coordinated approach, the Commission should ensure coherence between the activities of the Committee established by this Directive and those of the Committee established by Directive 2004/52/EC of the European Parliament and of the Council of 29 April 2004 on the interoperability of electronic road toll systems in the Community ([4]), the Committee established by Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport ([5]), the Committee established by Directive 2007/46/EC and the Committee established by Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) ([6]).

(23) Since the objective of this Directive, namely to ensure the coordinated and coherent deployment of interoperable Intelligent Transport Systems throughout the Union cannot be sufficiently achieved by the Member States and/or the private sector and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(24) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interest of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Subject matter and scope

1. This Directive establishes a framework in support of the coordinated and coherent deployment and use of Intelligent Transport Systems (ITS) within the Union, in particular across the borders between the Member States, and sets out the general conditions necessary for that purpose.

2. This Directive provides for the development of specifications for actions within the priority areas referred to in Article 2, as well as for the development, where appropriate, of necessary standards.

3. This Directive shall apply to ITS applications and services in the field of road transport and to their interfaces with other modes of transport without prejudice to matters concerning national security or necessary in the interest of defence.

([1]) OJ L 3, 5.1.2005, p. 1.
([2]) OJ L 196, 24.7.2008, p. 1.
([3]) OJ L 184, 17.7.1999, p. 23.
([4]) OJ L 166, 30.4.2004, p. 124.
([5]) OJ L 370, 31.12.1985, p. 8.
([6]) OJ L 108, 25.4.2007, p. 1.

Article 2

Priority areas

1. For the purpose of this Directive the following shall constitute priority areas for the development and use of specifications and standards:

— I. Optimal use of road, traffic and travel data,

— II. Continuity of traffic and freight management ITS services,

— III. ITS road safety and security applications,

— IV. Linking the vehicle with the transport infrastructure.

2. The scope of the priority areas is specified in Annex I.

Article 3

Priority actions

Within the priority areas the following shall constitute priority actions for the development and use of specifications and standards, as set out in Annex I:

(a) the provision of EU-wide multimodal travel information services;

(b) the provision of EU-wide real-time traffic information services;

(c) data and procedures for the provision, where possible, of road safety related minimum universal traffic information free of charge to users;

(d) the harmonised provision for an interoperable EU-wide eCall;

(e) the provision of information services for safe and secure parking places for trucks and commercial vehicles;

(f) the provision of reservation services for safe and secure parking places for trucks and commercial vehicles.

Article 4

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) 'Intelligent Transport Systems' or 'ITS' means systems in which information and communication technologies are applied in the field of road transport, including infrastructure, vehicles and users, and in traffic management and mobility management, as well as for interfaces with other modes of transport;

(2) 'interoperability' means the capacity of systems and the underlying business processes to exchange data and to share information and knowledge;

(3) 'ITS application' means an operational instrument for the application of ITS;

(4) 'ITS service' means the provision of an ITS application through a well-defined organisational and operational framework with the aim of contributing to user safety, efficiency, comfort and/or to facilitate or support transport and travel operations;

(5) 'ITS service provider' means any provider of an ITS service, whether public or private;

(6) 'ITS user' means any user of ITS applications or services including travellers, vulnerable road users, road transport infrastructure users and operators, fleet managers and operators of emergency services;

(7) 'vulnerable road users' means non-motorised road users, such as pedestrians and cyclists as well as motor-cyclists and persons with disabilities or reduced mobility and orientation;

(8) 'nomadic device' means a portable communication or information device that can be brought inside the vehicle to support the driving task and/or the transport operations;

(9) 'platform' means an on-board or off-board unit enabling the deployment, provision, exploitation and integration of ITS applications and services;

(10) 'architecture' means the conceptual design that defines the structure, behaviour and integration of a given system in its surrounding context;

(11) 'interface' means a facility between systems which provides the media through which they can connect and interact;

(12) 'compatibility' means the general ability of a device or system to work with another device or system without modification;

(13) 'continuity of services' means the ability to ensure seamless services on transport networks across the Union;

(14) 'road data' means data on road infrastructure characteristics, including fixed traffic signs or their regulatory safety attributes;

(15) 'traffic data' means historic and real-time data on road traffic characteristics;

(16) 'travel data' means basic data such as public transport timetables and tariffs, necessary to provide multi-modal travel information before and during the trip to facilitate travel planning, booking and adaptation;

(17) 'specification' means a binding measure laying down provisions containing requirements, procedures or any other relevant rules;

(18) 'standard' means standard as defined in Article 1(6) of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations [1].

Article 5

Deployment of ITS

1. Member States shall take the necessary measures to ensure that the specifications adopted by the Commission in accordance with Article 6 are applied to ITS applications and services, when these are deployed, in accordance with the principles in Annex II. This is without prejudice to the right of each Member State to decide on its deployment of such applications and services on its territory. This right is without prejudice to any legislative act adopted under the second subparagraph of Article 6(2).

2. Member States shall also make efforts to cooperate in respect of the priority areas, insofar as no specifications have been adopted.

Article 6

Specifications

1. The Commission shall first adopt the specifications necessary to ensure the compatibility, interoperability and continuity for the deployment and operational use of ITS for the priority actions.

2. The Commission shall aim at adopting specifications for one or more of the priority actions by 27 February 2013.

At the latest 12 months after the adoption of the necessary specifications for a priority action, the Commission shall, where appropriate, after conducting an impact assessment including a cost-benefit analysis, present a proposal to the European Parliament and the Council in accordance with Article 294 of the TFEU on the deployment of that priority action.

3. Once the necessary specifications for the priority actions have been adopted, the Commission shall adopt specifications ensuring compatibility, interoperability and continuity for the deployment and operational use of ITS for other actions in the priority areas.

4. Where relevant, and depending on the area covered by the specification, the specification shall include one or more of the following types of provisions:

(a) functional provisions that describe the roles of the various stakeholders and the information flow between them;

(b) technical provisions that provide for the technical means to fulfil the functional provisions;

(c) organisational provisions that describe the procedural obligations of the various stakeholders;

(d) service provisions that describe the various levels of services and their content for ITS applications and services.

5. Without prejudice to the procedures under Directive 98/34/EC the specifications shall, where appropriate, stipulate the conditions in which Member States may, after notification to the Commission, establish additional rules for the provision of ITS services on all or part of their territory, provided that those rules do not hinder interoperability.

6. The specifications shall, where appropriate, be based on any standards referred to in Article 8.

The specifications shall, as appropriate, provide for conformity assessment in accordance with Decision No 768/2008/EC.

The specifications shall comply with the principles set out in Annex II.

7. The Commission shall conduct an impact assessment including a cost-benefit analysis prior to the adoption of the specifications.

Article 7

Delegated acts

1. The Commission may adopt delegated acts in accordance with Article 290 of the TFEU as regards specifications. When adopting such delegated acts the Commission shall act in accordance with the relevant provisions of this Directive, in particular Article 6 and Annex II.

2. A separate delegated act shall be adopted for each of the priority actions.

3. For the delegated acts referred to in this Article, the procedure set out in Articles 12, 13 and 14 shall apply.

[1] OJ L 204, 21.7.1998, p. 37.

Article 8

Standards

1. The necessary standards to provide for interoperability, compatibility and continuity for the deployment and operational use of ITS shall be developed in the priority areas and for the priority actions. To that effect, the Commission, after having consulted the Committee referred to in Article 15, shall request the relevant standardisation bodies in accordance with the procedure laid down in Directive 98/34/EC to make every necessary effort to adopt these standards rapidly.

2. When issuing a mandate to the standardisation bodies, the principles set out in Annex II shall be observed as well as any functional provision included in a specification adopted in accordance with Article 6.

Article 9

Non-binding measures

The Commission may adopt guidelines and other non-binding measures to facilitate Member States' cooperation relating to the priority areas in accordance with the advisory procedure referred to in Article 15(2).

Article 10

Rules on privacy, security and re-use of information

1. Member States shall ensure that the processing of personal data in the context of the operation of ITS applications and services is carried out in accordance with Union rules protecting fundamental rights and freedoms of individuals, in particular Directive 95/46/EC and Directive 2002/58/EC.

2. In particular, Member States shall ensure that personal data are protected against misuse, including unlawful access, alteration or loss.

3. Without prejudice to paragraph 1, in order to ensure privacy, the use of anonymous data shall be encouraged, where appropriate, for the performance of the ITS applications and services.

Without prejudice to Directive 95/46/EC personal data shall only be processed insofar as such processing is necessary for the performance of ITS applications and services.

4. With regard to the application of Directive 95/46/EC and in particular where special categories of personal data are involved, Member States shall also ensure that the provisions on consent to the processing of such personal data are respected.

5. Directive 2003/98/EC shall apply.

Article 11

Rules on liability

Member States shall ensure that issues related to liability, concerning the deployment and use of ITS applications and services set out in specifications adopted in accordance with Article 6, are addressed in accordance with Union law, including in particular 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 [1] as well as relevant national legislation.

Article 12

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Article 7 shall be conferred on the Commission for a period of seven years following 27 August 2010. The Commission shall make a report in respect of the delegated powers no later than six months before the end of a five year period following 27 August 2010.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 13 and 14.

Article 13

Revocation of the delegation

1. The delegation of powers referred to in Article 7 may be revoked by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

[1] OJ L 210, 7.8.1985, p. 29.

Article 14

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by two months.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 15

Committee procedure

1. The Commission shall be assisted by the European ITS Committee (EIC).

2. Where reference is made to this paragraph, Article 3 and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 16

European ITS Advisory Group

The Commission shall establish a European ITS Advisory Group to advise it on business and technical aspects of the deployment and use of ITS in the Union. The group shall be composed of high level representatives from relevant ITS service providers, associations of users, transport and facilities operators, manufacturing industry, social partners, professional associations, local authorities and other relevant fora.

Article 17

Reporting

1. Member States shall submit to the Commission by 27 August 2011 a report on their national activities and projects regarding the priority areas.

2. Member States shall provide the Commission by 27 August 2012 with information on national ITS actions envisaged over the following five year period.

Guidelines for reporting by the Member States shall be adopted in accordance with the advisory procedure referred to in Article 15(2).

3. Following the initial report, Member States shall report every three years on the progress made in the deployment of the actions referred to in paragraph 1.

4. The Commission shall submit a report every three years to the European Parliament and to the Council on the progress made for the implementation of this Directive. The report shall be accompanied by an analysis on the functioning and implementation, including the financial resources used and needed, of Articles 5 to 11 and Article 16, and shall assess the need to amend this Directive, where appropriate.

5. In accordance with the advisory procedure referred to in Article 15(2), the Commission shall adopt a working program by 27 February 2011. The working program shall include objectives and dates for its implementation every year and if necessary shall propose the necessary adaptations.

Article 18

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 27 February 2012.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference, and its wording, shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 19

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 20

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 7 July 2010.

For the European Parliament	*For the Council*
The President	*The President*
J. BUZEK	O. CHASTEL

ANNEX I

PRIORITY AREAS AND ACTIONS

(as referred to in Articles 2 and 3)

— **Priority area I: Optimal use of road, traffic and travel data**

The specifications and standards for an optimal use of road, traffic and travel data shall include the following:

1. Specifications for priority action (a)

The definition of the necessary requirements to make EU-wide multimodal travel information services accurate and available across borders to ITS users, based on:

— the availability and accessibility of existing and accurate road and real-time traffic data used for multimodal travel information to ITS service providers without prejudice to safety and transport management constraints,

— the facilitation of the electronic data exchange between the relevant public authorities and stakeholders and the relevant ITS service providers, across borders,

— the timely updating of available road and traffic data used for multimodal travel information by the relevant public authorities and stakeholders,

— the timely updating of multimodal travel information by the ITS service providers.

2. Specifications for priority action (b)

The definition of the necessary requirements to make EU-wide real-time traffic information services accurate and available across borders to ITS users, based on:

— the availability and accessibility of existing and accurate road and real-time traffic data used for real-time traffic information to ITS service providers without prejudice to safety and transport management constraints,

— the facilitation of the electronic data exchange between the relevant public authorities and stakeholders and the relevant ITS service providers, across borders,

— the timely updating of available road and traffic data used for real-time traffic information by the relevant public authorities and stakeholders,

— the timely updating of real-time traffic information by the ITS service providers.

3. Specifications for priority actions (a) and (b)

3.1. The definition of the necessary requirements for the collection by relevant public authorities and/or, where relevant, by the private sector of road and traffic data (i.e. traffic circulation plans, traffic regulations and recommended routes, notably for heavy goods vehicles) and for their provisioning to ITS service providers, based on:

— the availability, to ITS service providers, of existing road and traffic data (i.e. traffic circulation plans, traffic regulations and recommended routes) collected by the relevant public authorities and/or the private sector,

— the facilitation of the electronic data exchange between the relevant public authorities and the ITS service providers,

— the timely updating, by the relevant public authorities and/or, where relevant, the private sector, of road and traffic data (i.e. traffic circulation plans, traffic regulations and recommended routes),

— the timely updating, by the ITS service providers, of the ITS services and applications using these road and traffic data.

3.2. The definition of the necessary requirements to make road, traffic and transport services data used for digital maps accurate and available, where possible, to digital map producers and service providers, based on:

— the availability of existing road and traffic data used for digital maps to digital map producers and service providers,

— the facilitation of the electronic data exchange between the relevant public authorities and stakeholders and the private digital map producers and service providers,

— the timely updating of road and traffic data for digital maps by the relevant public authorities and stakeholders,

— the timely updating of the digital maps by the digital map producers and service providers.

4. Specifications for priority action (c)

The definition of minimum requirements, for road safety related 'universal traffic information' provided, where possible, free of charge to all users, as well as their minimum content, based on:

— the identification and use of a standardised list of safety related traffic events ('universal traffic messages') which should be communicated to ITS users free of charge,

— The compatibility and the integration of 'universal traffic messages' into ITS services for real-time traffic and multimodal travel information.

— **Priority area II: Continuity of traffic and freight management ITS services**

The specifications and standards for the continuity and interoperability of traffic and freight management services, in particular on the TEN-T network, shall include the following:

1. Specifications for other actions

1.1. The definition of the necessary measures to develop an EU ITS Framework Architecture, addressing specifically ITS-related interoperability, continuity of services and multi-modality aspects, including for example multimodal interoperable ticketing, within which Member States and their competent authorities in cooperation with the private sector can develop their own ITS architecture for mobility at national, regional or local level.

1.2. The definition of the minimum necessary requirements for the continuity of ITS services, in particular for cross-border services, for the management of passenger transport across different modes of transport, based on:

— the facilitation of the electronic exchange for traffic data and information across borders, and where appropriate, regions, or between urban and inter-urban areas between the relevant traffic information/control centres and different stakeholders,

— the use of standardised information flows or traffic interfaces between the relevant traffic information/control centres and different stakeholders.

1.3. The definition of the minimum necessary requirements for the continuity of ITS services for the management of freight along transport corridors and across different modes of transport, based on:

— the facilitation of the electronic exchange for traffic data and information across borders, and where appropriate, regions, or between urban and inter-urban areas between the relevant traffic information/control centres and different stakeholders,

— the use of standardised information flows or traffic interfaces between the relevant traffic information/control centres and different stakeholders.

1.4. The definition of the necessary measures in the realisation of ITS applications (notably the tracking and tracing of freight along its journey and across modes of transport) for freight transport logistics (eFreight), based on:

— the availability of relevant ITS technologies to and their use by ITS application developers,

— the integration of positioning results in the traffic management tools and centres.

1.5. The definition of the necessary interfaces to ensure interoperability and compatibility between the urban ITS architecture and the European ITS architecture based on:

— the availability of public transport, travel planning, transport demand, traffic data and parking data to urban control centres and service providers,

— the facilitation of the electronic data exchange between the different urban control centres and service providers for public or private transport and through all possible modes of transport,

— the integration of all relevant data and information in a single architecture.

— **Priority area III: ITS road safety and security applications**

The specifications and standards for ITS road safety and security applications shall include the following:

1. Specifications for priority action (d)

The definition of the necessary measures for the harmonised provision of an interoperable EU-wide eCall, including:

— the availability of the required in-vehicle ITS data to be exchanged,

— the availability of the necessary equipment in the emergency call response centres receiving the data emitted from the vehicles,

— the facilitation of the electronic data exchange between the vehicles and the emergency call response centres.

2. Specifications for priority action (e)

The definition of the necessary measures to provide ITS based information services for safe and secure parking places for trucks and commercial vehicles, in particular in service and rest areas on roads, based on:

— the availability of the road parking information to users,

— the facilitation of the electronic data exchange between road parking sites, centres and vehicles.

3. Specifications for priority action (f)

The definition of the necessary measures to provide ITS based reservation services for safe and secure parking places for trucks and commercial vehicles based on:

— the availability of the road parking information to users,

— the facilitation of the electronic data exchange between road parking sites, centres and vehicles,

— the integration of relevant ITS technologies in both vehicles and road parking facilities to update the information on available parking space for reservation purposes.

4. Specifications for other actions

4.1. The definition of the necessary measures to support the safety of road users with respect to their on-board Human-Machine-Interface and the use of nomadic devices to support the driving task and/or the transport operation, as well as the security of the in-vehicle communications.

4.2. The definition of the necessary measures to improve the safety and comfort of vulnerable road users for all relevant ITS applications.

4.3. The definition of necessary measures to integrate advanced driver support information systems into vehicles and road infrastructure which fall outside the scope of Directives 2007/46/EC, 2002/24/EC and 2003/37/EC.

— **Priority area IV: Linking the vehicle with the transport infrastructure**

The specifications and standards for linking vehicles with the transport infrastructure shall include the following:

1. Specifications for other actions

1.1. The definition of necessary measures to integrate different ITS applications on an open in-vehicle platform, based on:

— the identification of functional requirements of existing or planned ITS applications,

— the definition of an open-system architecture which defines the functionalities and interfaces necessary for the interoperability/interconnection with infrastructure systems and facilities,

— the integration of future new or upgraded ITS applications in a 'plug and play' manner into an open in-vehicle platform,

— the use of a standardisation process for the adoption of the architecture, and the open in-vehicle specifications.

1.2. The definition of necessary measures to further progress the development and implementation of cooperative (vehicle-vehicle, vehicle-infrastructure, infrastructure-infrastructure) systems, based on:

— the facilitation of the exchange of data or information between vehicles, infrastructures and between vehicle and infrastructure,

— the availability of the relevant data or information to be exchanged to the respective vehicle or road infrastructure parties,

— the use of a standardised message format for the exchange of data or information between the vehicle and the infrastructure,

— the definition of a communication infrastructure for data or information exchange between vehicles, infrastructures and between vehicle and infrastructure,

— the use of standardisation processes to adopt the respective architectures.

ANNEX II

PRINCIPLES FOR SPECIFICATIONS AND DEPLOYMENT OF ITS

(as referred to in Articles 5, 6 and 8)

The adoption of specifications, the issuing of mandates for standards and the selection and deployment of ITS applications and services shall be based upon an evaluation of needs involving all relevant stakeholders, and shall comply with the following principles. These measures shall:

(a) **Be effective** – make a tangible contribution towards solving the key challenges affecting road transportation in Europe (e.g. reducing congestion, lowering of emissions, improving energy efficiency, attaining higher levels of safety and security including vulnerable road users);

(b) **Be cost-efficient** – optimise the ratio of costs in relation to output with regard to meeting objectives;

(c) **Be proportionate** – provide, where appropriate, for different levels of achievable service quality and deployment, taking into account the local, regional, national and European specificities;

(d) **Support continuity of services** – ensure seamless services across the Union, in particular on the trans-European network, and where possible at its external borders, when ITS services are deployed. Continuity of services should be ensured at a level adapted to the characteristics of the transport networks linking countries with countries, and where appropriate, regions with regions and cities with rural areas;

(e) **Deliver interoperability** – ensure that systems and the underlying business processes have the capacity to exchange data and to share information and knowledge to enable effective ITS service delivery;

(f) **Support backward compatibility** – ensure, where appropriate, the capability for ITS systems to work with existing systems that share a common purpose, without hindering the development of new technologies;

(g) **Respect existing national infrastructure and network characteristics** – take into account the inherent differences in the transport network characteristics, in particular in the sizes of the traffic volumes and in road weather conditions;

(h) **Promote equality of access** – do not impede or discriminate against access to ITS applications and services by vulnerable road users;

(i) **Support maturity** – demonstrate, after appropriate risk assessment, the robustness of innovative ITS systems, through a sufficient level of technical development and operational exploitation;

(j) **Deliver quality of timing and positioning** – use of satellite-based infrastructures, or any technology providing equivalent levels of precision for the purposes of ITS applications and services that require global, continuous, accurate and guaranteed timing and positioning services;

(k) **Facilitate inter-modality** – take into account the coordination of various modes of transport, where appropriate, when deploying ITS;

(l) **Respect coherence** – take into account existing Union rules, policies and activities which are relevant in the field of ITS, in particular in the field of standardisation.

DIRECTIVE 2010/45/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 7 July 2010

on standards of quality and safety of human organs intended for transplantation

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Having regard to the opinion of the European Data Protection Supervisor [2],

Acting in accordance with the ordinary legislative procedure [3],

Whereas:

(1) Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs (hereinafter 'organs') for transplantation has steadily increased during the last two decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment.

(2) Risks are, however, associated with the use of organs in transplantation. The extensive therapeutic use of organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases. Well organised national and international transplantation systems and use of the best available expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs for recipients.

(3) In addition the availability of organs used for therapeutic purposes is dependent on citizens of the Union being prepared to donate them. In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures should be taken during their procurement, transport and use.

(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of increasing the number of organs available and ensuring a better match between donor and recipient and therefore improving the quality of the transplantation. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatment, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

(5) However, transplantation is carried out by hospitals or professionals falling under different jurisdictions and there are significant differences in quality and safety requirements between Member States.

(6) There is therefore a need for common quality and safety standards for the procurement, transport and use of organs at Union level. Such standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Union legislation should ensure that organs comply with recognised standards of quality and safety. Such standards would help to reassure the public that organs procured in another Member State carry the same basic quality and safety guarantees as those obtained in their own country.

(7) Unacceptable practices in organ donation and transplantation include trafficking in organs, sometimes linked to trafficking in persons for the purpose of the removal of organs, which constitutes a serious violation of fundamental rights and, in particular, of human dignity and physical integrity. This Directive, although having as its first objective the safety and quality of organs, contributes indirectly to combating organ trafficking through the establishment of competent authorities, the authorisation of transplantation centres, the establishment of conditions of procurement and systems of traceability.

[1] OJ C 306, 16.12.2009, p. 64.
[2] OJ C 192, 15.8.2009, p. 6.
[3] Position of the European Parliament of 19 May 2010 (not yet published in the Official Journal) and decision of the Council of 29 June 2010.

(8) According to Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the measures adopted pursuant to Article 168(4)(a) thereof shall not affect national provisions on the medical use of organs, nor therefore the surgical act of transplantation itself. However, in view of the objective of reducing the associated risks of the transplanted organs, it is necessary to include in the scope of this Directive certain provisions concerning transplantation and, in particular, provisions aimed at addressing those unintended and unexpected situations occurring during the transplantation that might affect the quality and safety of organs.

(9) In order to reduce the risks and maximise the benefits of transplantation, Member States need to operate an effective framework for quality and safety. That framework should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the healthcare personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The framework for quality and safety should include auditing where necessary. Member States should be able to delegate the performance of activities provided for under the framework for quality and safety to specific bodies deemed appropriate under national provisions, including European organ exchange organisations.

(10) Competent authorities should supervise compliance with the conditions of procurement through the authorisation of procurement organisations. Such organisations should have in place proper organisation, suitably qualified or trained and competent personnel and adequate facilities and material.

(11) The risk-benefit ratio is a fundamental aspect of organ transplantation. Owing to the shortage of organs and the inherent life-threatening nature of diseases leading to the need for organs for transplantation, the overall benefits of organ transplantation are high and more risks are accepted than with blood or most tissues and cell-based treatments. The clinician plays an important role in this context by deciding whether or not organs are suitable for transplantation. This Directive sets out the information required to make that assessment.

(12) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. That evaluation has to provide enough information for the transplantation centre to undertake a proper risk-benefit analysis. It is necessary to identify and document the risks and characteristics of the organ in order to allow its allocation to a suitable recipient. Information from a potential donor's medical history, physical examination and complementary tests should be collected for the adequate characterisation of the organ and the donor. To obtain an accurate, reliable and objective history, the medical team should perform an interview with the living donor or, where necessary and appropriate, with the relatives of the deceased donor, during which the team should properly inform them about the potential risks and consequences of donation and transplantation. Such an interview is particularly important due to the time constraints in the process of deceased donation which reduce the ability to rule out potentially serious transmissible diseases.

(13) The shortage of organs available for transplantation and the time constraints in the process of organ donation and transplantation make it necessary to take into account those situations in which the transplantation team lacks some of the information required for organ and donor characterisation as set out in Part A of the Annex, which specifies a mandatory minimum data set. In those particular cases, the medical team should assess the particular risk posed to the potential recipient by the lack of information and by not proceeding with transplantation of the organ in question. Where a complete characterisation of an organ, according to Part A of the Annex, is not possible in time or due to particular circumstances, the organ may be considered for transplantation where non-transplantation might pose a greater risk to the potential recipient. Part B of the Annex, referring to a complementary data set, should allow a more detailed organ and donor characterisation to be made.

(14) Effective rules for the transportation of organs should be provided that optimise ischaemic times and reduce organ damage. While maintaining medical confidentiality, the organ container should be clearly labelled and accompanied by the necessary documentation.

(15) The transplantation system should ensure traceability of organs from donation to reception and should have the capacity to raise the alert if there is any unexpected complication. A system should therefore be put in place to detect and investigate serious adverse events and reactions for the protection of vital interest of the individuals concerned.

(16) An organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing Union system for tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [1]. This does not mean that systems for organs and for tissues and cells should necessarily be electronically linked. An unexpected adverse reaction in an organ donor or recipient should be traced by the competent authority and reported through the notification system for serious adverse events and reactions for tissues and cells as provided for in that Directive.

[1] OJ L 102, 7.4.2004, p. 48.

(17) Healthcare personnel directly involved in the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs should be suitably qualified or trained and competent. The importance of donor coordinators, appointed at hospital level, has been acknowledged by the Council of Europe. The role of the donor coordinator or coordination team should be recognised as key to improving not only the effectiveness of the process of donation and transplantation, but also the quality and safety of the organs to be transplanted.

(18) As a general principle, organ exchange with third countries should be supervised by the competent authority. Organ exchange with third countries should be allowed only where standards equivalent to those provided for in this Directive are met. However, the important role played by existing European organ exchange organisations in the exchange of organs between the Member States and third countries participating in such organisations should be taken into account.

(19) Altruism is an important factor in organ donations. To ensure the quality and safety of organs, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation. This is essential because the violation of these principles might be associated with unacceptable risks. Where donation is not voluntary and/or is undertaken with a view to financial gain, the quality of the process of donation could be jeopardised because improving the quality of life or saving the life of a person is not the main and/or the unique objective. Even if the process is developed in accordance with appropriate quality standards, a clinical history obtained from either a potential living donor or the relatives of a potential deceased donor who are seeking financial gain or are subjected to any kind of coercion might not be sufficiently accurate in terms of conditions and/or diseases potentially transmissible from donor to recipient. This could give rise to a safety problem for potential recipients since the medical team would have a limited capability for performing an appropriate risk assessment. The Charter of Fundamental Rights of the European Union should be recalled, notably the principle set out in Article 3(2)(c) thereof. That principle is also enshrined in Article 21 of the Convention on Human Rights and Biomedicine of the Council of Europe, which many Member States have ratified. It is also reflected in the World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation, whereby the human body and its parts may not be the subject of commercial transactions.

(20) Other internationally recognised principles guiding practices in organ donation and transplantation include, inter alia, the certification or the confirmation of death in accordance with national provisions before the procurement of organs from deceased persons and the allocation of organs based on transparent, non-discriminatory and scientific criteria. They should be recalled and be taken into account in the context of the Commission's Action Plan on Organ Donation and Transplantation.

(21) Several models of consent to donation coexist in the Union, including opting-in systems in which consent to organ donation has to be explicitly obtained, and opting-out systems in which donation can take place unless there is evidence of any objection to donation. In order to enable individuals to express their wishes in this regard, some Member States have developed specific registries where citizens record them. This Directive is without prejudice to the broad diversity of the systems of consent already in place in the Member States. In addition, by means of its Action plan on Organ Donation and Transplantation the Commission aims to increase public awareness of organ donation and in particular to develop mechanisms to facilitate the identification of organ donors across Europe.

(22) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] prohibits in principle the processing of data concerning health, while laying down limited exemptions. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing. It should be ensured that strict confidentiality rules and security measures are in place for the protection of donors' and recipients' personal data, in accordance with Directive 95/46/EC. Moreover, the competent authority may also consult the national data protection supervisory authority in relation to developing a framework for the transfer of data on organs to and from third countries. As a general principle, the identity of the recipient(s) should not be disclosed to the donor or the donor's family or vice versa, without prejudice to legislation in force in Member States which, under specific conditions, might allow such information to be made available to donors or donors' families and organ recipients.

[1] OJ L 281, 23.11.1995, p. 31.

(23) Living donation coexists with deceased donation in most Member States. Living donation has evolved over the years in such a way that good results can be obtained even where there is no genetic relationship between donor and recipient. Living donors should be adequately evaluated to determine their suitability for donation in order to minimise the risk of transmission of diseases to the recipients. In addition, living donors face risks linked both to testing to ascertain their suitability as a donor and to the procedure to obtain the organ. Complications may be medical, surgical, social, financial or psychological. The level of risk depends, in particular, on the type of organ to be donated. Therefore, living donations need to be performed in a manner that minimises the physical, psychological and social risk to the individual donor and the recipient and does not jeopardise the public's trust in the healthcare community. The potential living donor has to be able to take an independent decision on the basis of all the relevant information and should be informed in advance as to the purpose and nature of the donation, the consequences and risks. In this context, and to guarantee respect for the principles governing donation, the highest possible protection of living donors should be ensured. It should also be noted that some Member States are signatories to the Convention on Human Rights and Biomedicine of the Council of Europe, and its additional protocol on Transplantation of Organs and Tissues of Human Origin. Complete information, a proper evaluation and an adequate follow-up are internationally recognised measures aimed at protecting the living donors and also contribute to ensuring the quality and safety of organs.

(24) The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation and in evaluating their quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, besides the system for reporting serious adverse events and reactions, the collection of relevant post-transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation. Sharing such information between Member States would facilitate further improvement of donation and transplantation across the Union. As emphasised by the Recommendation Rec(2006)15 of the Committee of Ministers of the Council of Europe to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO), it is preferable to have a single non-profit making body which is officially recognised with overall responsibility for donation, allocation, traceability and accountability. However, depending especially on the division of competences within the Member States, a combination of local, regional, national and/or international bodies may work together to coordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, cooperation and efficiency.

(25) Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that these penalties are implemented. Those penalties should be effective, proportionate and dissuasive.

(26) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to adapt the Annex. The Commission should supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health, and supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(27) The exchange of organs between Member States requires that uniform rules on the procedures for the transmission of information on organs and donor characterisation, as well as for ensuring the traceability of organs and for reporting serious adverse events and reactions, should be adopted by the Commission, in order to ensure the highest standards of quality and safety of the organs exchanged. According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1] continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(28) Since the objectives of this Directive, namely laying down quality and safety standards for organs intended for transplantation to the human body, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

[1] OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject Matter

This Directive lays down rules to ensure standards of quality and safety for human organs (hereinafter 'organs') intended for transplantation to the human body, in order to ensure a high level of human health protection.

Article 2

Scope

1. This Directive applies to the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation.

2. Where such organs are used for research purposes, this Directive only applies where they are intended for transplantation into the human body.

Article 3

Definitions

For the purposes of this Directive, the following definitions apply:

(a) 'authorisation' means authorisation, accreditation, designation, licensing or registration, depending on the concepts used and the practices in place in each Member State;

(b) 'competent authority' means an authority, body, organisation and/or institution responsible for implementing the requirements of this Directive;

(c) 'disposal' means the final placement of an organ where it is not used for transplantation;

(d) 'donor' means a person who donates one or several organs, whether donation occurs during lifetime or after death;

(e) 'donation' means donating organs for transplantation;

(f) 'donor characterisation' means the collection of the relevant information on the characteristics of the donor needed to evaluate his/her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

(g) 'European organ exchange organisation' means a non-profit organisation, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its member countries are Member States;

(h) 'organ' means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

(i) 'organ characterisation' means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

(j) 'procurement' means a process by which the donated organs become available;

(k) 'procurement organisation' means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the competent authority under the regulatory framework in the Member State concerned;

(l) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

(m) 'recipient' means a person who receives a transplant of an organ;

(n) 'serious adverse event' means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

(o) 'serious adverse reaction' means an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

(p) 'operating procedures' means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

(q) 'transplantation' means a process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient;

(r) 'transplantation centre' means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the competent authority under the regulatory framework in the Member State concerned;

(s) 'traceability' means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to:

— identify the donor and the procurement organisation,

— identify the recipient(s) at the transplantation centre(s), and

— locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.

CHAPTER II

THE QUALITY AND SAFETY OF ORGANS

Article 4

Framework for quality and safety

1. Member States shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in this Directive.

2. The framework for quality and safety shall provide for the adoption and implementation of operating procedures for:

(a) the verification of donor identity;

(b) the verification of the details of the donor's or the donor's family's consent, authorisation or absence of any objection, in accordance with the national rules that apply where donation and procurement take place;

(c) the verification of the completion of the organ and donor characterisation in accordance with Article 7 and the Annex;

(d) the procurement, preservation, packaging and labelling of organs in accordance with Articles 5, 6 and 8;

(e) the transportation of organs in accordance with Article 8;

(f) ensuring traceability, in accordance with Article 10, guaranteeing compliance with the Union and national provisions on the protection of personal data and confidentiality;

(g) the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1);

(h) the management of serious adverse events and reactions in accordance with Article 11(2).

The operating procedures referred to in points (f), (g) and (h) shall specify, inter alia, the responsibilities of procurement organisations, European organ exchange organisations and transplantation centres.

3. In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

Article 5

Procurement organisations

1. Member States shall ensure that the procurement takes place in, or is carried out by, procurement organisations that comply with the rules laid down in this Directive.

2. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of procurement organisations.

Article 6

Organ procurement

1. Member States shall ensure that medical activities in procurement organisations, such as donor selection and evaluation, are performed under the advice and the guidance of a doctor of medicine as referred to in Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications [1].

[1] OJ L 255, 30.9.2005, p. 22.

2. Member States shall ensure that procurement takes place in operating theatres, which are designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured.

3. Member States shall ensure that procurement material and equipment are managed in accordance with relevant Union, international and national legislation, standards and guidelines on the sterilisation of medical devices.

Article 7

Organ and donor characterisation

1. Member States shall ensure that all procured organs and donors thereof are characterised before transplantation through the collection of the information set out in the Annex.

The information specified in Part A of the Annex contains a set of minimum data which has to be collected for each donation. Information specified in Part B of the Annex contains a set of complementary data to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

2. Notwithstanding paragraph 1, if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the Annex are available.

3. In order to meet the quality and safety requirements laid down in this Directive, the medical team shall endeavour to obtain all necessary information from living donors and for that purpose shall provide them with the information they need to understand the consequences of donation. In the case of deceased donation, where possible and appropriate, the medical team shall endeavour to obtain such information from relatives of the deceased donor or other persons. The medical team shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of that information.

4. The tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.

5. Member States shall ensure that organisations, bodies and laboratories involved in organ and donor characterisation have appropriate operating procedures in place to ensure that the information on organ and donor characterisation reaches the transplantation centre in due time.

6. Where organs are exchanged between Member States, those Member States shall ensure that the information on organ and donor characterisation, as specified in the Annex, is transmitted to the other Member State with which the organ is exchanged, in conformity with the procedures established by the Commission pursuant to Article 29.

Article 8

Transport of organs

1. Member States shall ensure that the following requirements are met:

(a) the organisations, bodies or companies involved in the transportation of organs have appropriate operating procedures in place to ensure the integrity of the organs during transport and a suitable transport time;

(b) the shipping containers used for transporting organs are labelled with the following information:

(i) identification of the procurement organisation and the establishment where the procurement took place, including their addresses and telephone numbers;

(ii) identification of the transplantation centre of destination, including its address and telephone number;

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked 'HANDLE WITH CARE';

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position;

(c) the organs transported are accompanied by a report on the organ and donor characterisation.

2. The requirements laid down in paragraph 1(b) need not be met where the transportation is carried out within the same establishment.

Article 9

Transplantation centres

1. Member States shall ensure that transplantation takes place in, or is carried out by, transplantation centres that comply with the rules laid down in this Directive.

2. The competent authority shall indicate in the authorisation which activities the transplantation centre concerned may undertake.

3. The transplantation centre shall verify before proceeding to transplantation that:

(a) the organ and donor characterisation are completed and recorded in accordance with Article 7 and the Annex;

(b) the conditions of preservation and transport of shipped organs have been maintained.

4. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres.

Article 10

Traceability

1. Member States shall ensure that all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients.

2. Member States shall ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it. With regard to such a system, Member States shall ensure that confidentiality and data security measures are in place in compliance with Union and national provisions, as referred to in Article 16.

3. Member States shall ensure that:

(a) the competent authority or other bodies involved in the chain from donation to transplantation or disposal keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in the Annex, in accordance with the framework for quality and safety;

(b) data required for full traceability is kept for a minimum of 30 years after donation. Such data may be stored in electronic form.

4. Where organs are exchanged between Member States, those Member States shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission pursuant to Article 29.

Article 11

Reporting system and management concerning serious adverse events and reactions

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

2. Member States shall ensure that an operating procedure is in place for the management of serious adverse events and reactions as provided for in the framework for quality and safety.

3. In particular, and with regard to paragraphs 1 and 2, Member States shall ensure that operating procedures are in place for the notification, in due time, of:

(a) any serious adverse event and reaction to the competent authority and to the concerned procurement organisation or transplantation centre;

(b) the management measures with regard to serious adverse events and reactions to the competent authority.

4. Where organs are exchanged between Member States, those Member States shall ensure the reporting of serious adverse events and reactions in conformity with the procedures established by the Commission pursuant to Article 29.

5. Member States shall ensure the interconnection between the reporting system referred to in paragraph 1 of this Article and the notification system established in accordance with Article 11(1) of Directive 2004/23/EC.

Article 12

Healthcare personnel

Member States shall ensure that healthcare personnel directly involved in the chain from donation to the transplantation or disposal of organs are suitably qualified or trained and competent to perform their tasks and are provided with the relevant training, as referred to in Article 4(3).

CHAPTER III

DONOR AND RECIPIENT PROTECTION AND DONOR SELECTION AND EVALUATION

Article 13

Principles governing organ donation

1. Member States shall ensure that donations of organs from deceased and living donors are voluntary and unpaid.

2. The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation. Member States shall define the conditions under which such compensation may be granted, while avoiding there being any financial incentives or benefit for a potential donor.

3. Member States shall prohibit advertising the need for, or availability of, organs where such advertising is with a view to offering or seeking financial gain or comparable advantage.

4. Member States shall ensure that the procurement of organs is carried out on a non-profit basis.

Article 14

Consent requirements

The procurement of organs shall be carried out only after all requirements relating to consent, authorisation or absence of any objection in force in the Member State concerned have been met.

Article 15

Quality and safety aspects of living donation

1. Member States shall take all necessary measures to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation.

2. Member States shall ensure that living donors are selected on the basis of their health and medical history, by suitably qualified or trained and competent professionals. Such assessments may provide for the exclusion of persons whose donation could present unacceptable health risks.

3. Member States shall ensure that a register or record of the living donors is kept, in accordance with Union and national provisions on the protection of the personal data and statistical confidentiality.

4. Member States shall endeavour to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.

Article 16

Protection of personal data, confidentiality and security of processing

Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with Union provisions on the protection of personal data, such as Directive 95/46/EC, and in particular Article 8(3), Articles 16 and 17 and Article 28(2) thereof. Pursuant to Directive 95/46/EC, Member States shall take all necessary measures to ensure that:

(a) the data processed are kept confidential and secure in accordance with Articles 16 and 17 of Directive 95/46/EC. Any unauthorised accessing of data or systems that makes identification of donor or recipients possible shall be penalised in accordance with Article 23 of this Directive;

(b) donors and recipients whose data are processed within the scope of this Directive are not identifiable, except as permitted by Article 8(2) and (3) of Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by Article 8(2) and (3) of Directive 95/46/EC, including medical purposes, and by national provisions implementing that Directive shall be penalised in accordance with Article 23 of this Directive;

(c) the principles relating to data quality, as set out in Article 6 of Directive 95/46/EC, are met.

CHAPTER IV

OBLIGATIONS OF COMPETENT AUTHORITIES AND EXCHANGE OF INFORMATION

Article 17

Designation and tasks of competent authorities

1. Member States shall designate one or more competent authorities.

Member States may delegate, or may allow a competent authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed suitable under national provisions. Such a body may also assist the competent authority in carrying out its functions.

2. The competent authority shall, in particular, take the following measures:

(a) establish and keep updated a framework for quality and safety in accordance with Article 4;

(b) ensure that procurement organisations and transplantations centres are controlled or audited on a regular basis to ascertain compliance with the requirements of this Directive;

(c) grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres or prohibit procurement organisations or transplantation centres from carrying out their activities where control measures demonstrate that such organisations or centres are not complying with the requirements of this Directive;

(d) put in place a reporting system and management procedure for serious adverse events and reactions as provided for in Article 11(1) and (2);

(e) issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted;

(f) participate, whenever possible, in the network of competent authorities referred to in Article 19 and coordinate at national level input to the activities of that network;

(g) supervise organ exchange with other Member States and with third countries as provided for in Article 20(1);

(h) ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with Union provisions on the protection of personal data, in particular Directive 95/46/EC.

Article 18

Records and reports concerning procurement organisations and transplantation centres

1. Member States shall ensure that the competent authority:

(a) keeps a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with Union and national provisions on the protection of personal data and statistical confidentiality;

(b) draws up and makes publicly accessible an annual report on activities referred to in point (a);

(c) establishes and maintains an updated record of procurement organisations and transplantation centres.

2. Member States shall, upon the request of the Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.

Article 19

Exchange of information

1. The Commission shall set up a network of the competent authorities with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.

2. Where appropriate, experts on organ transplantation, representatives from European organ exchange organisations, as well as data protection supervisory authorities and other relevant parties may be associated with this network.

CHAPTER V

ORGAN EXCHANGE WITH THIRD COUNTRIES AND EUROPEAN ORGAN EXCHANGE ORGANISATIONS

Article 20

Organ exchange with third countries

1. Member States shall ensure that organ exchange with third countries is supervised by the competent authority. For this purpose, the competent authority and European organ exchange organisations may conclude agreements with counterparts in third countries.

2. The supervision of organ exchange with third countries may be delegated by the Member States to European organ exchange organisations.

3. Organ exchange, as referred to in paragraph 1, shall be allowed only where the organs:

(a) can be traced from the donor to the recipient and vice versa;

(b) meet quality and safety requirements equivalent to those laid down in this Directive.

Article 21

European organ exchange organisations

Member States may conclude or allow a competent authority to conclude agreements with European organ exchange organisations, provided that such organisations ensure compliance with the requirements laid down in this Directive, delegating to those organisations, inter alia:

(a) the performance of activities provided for under the framework for quality and safety;

(b) specific tasks in relation to the exchanges of organs to and from Member States and third countries.

CHAPTER VI

GENERAL PROVISIONS

Article 22

Reports concerning this Directive

1. Member States shall report to the Commission before 27 August 2013 and every three years thereafter on the activities undertaken in relation to the provisions of this Directive, and on the experience gained in implementing it.

2. Before 27 August 2014 and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, a report on the implementation of this Directive.

Article 23

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 27 August 2012 and shall notify it without delay of any subsequent amendments affecting them.

Article 24

Adaptation of the Annex

The Commission may adopt delegated acts in accordance with Article 25 and subject to the conditions of Articles 26, 27 and 28 in order to:

(a) supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health considered as such on the basis of the scientific progress;

(b) supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation.

Article 25

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Article 24 shall be conferred on the Commission for a period of five years following 27 August 2010. The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 26.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 26 and 27.

4. Where, in the case of the emergence of new serious risk to human health, imperative grounds of urgency so require, the procedure provided for in Article 28 shall apply to delegated acts adopted pursuant to Article 24(a).

Article 26

Revocation of the delegation

1. The delegation of powers referred to in Article 24 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 27

Objection to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by two months.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 28

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act adopted under this Article to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. The European Parliament or the Council may object to a delegated act adopted under this Article in accordance with the procedure referred to in Article 27(1). In such a case, the act shall cease to apply. The institution which objects to such a delegated act shall state its reasons therefor.

Article 29

Implementing measures

The Commission shall adopt, where organs are exchanged between Member States, detailed rules for the uniform implementation of this Directive in accordance with the procedure referred to in Article 30(2), on the following:

(a) procedures for the transmission of information on organ and donor characterisation as specified in the Annex in accordance with Article 7(6);

(b) procedures for the transmission of the necessary information to ensure the traceability of organs in accordance with Article 10(4);

(c) procedures for ensuring the reporting of serious adverse events and reactions in accordance with Article 11(4).

Article 30

Committee

1. The Commission shall be assisted by the Committee on organ transplantation, hereinafter referred to as 'the Committee'.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

Article 31

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 27 August 2012. They shall forthwith inform the Commission thereof.

When they are adopted by Member States, those measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. This Directive shall not prevent any Member State from maintaining or introducing more stringent rules, provided that they comply with the provisions of the Treaty on the Functioning of the European Union.

3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

CHAPTER VII

FINAL PROVISIONS

Article 32

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 33

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 7 July 2010.

For the European Parliament	*For the Council*
The President	*The President*
J. BUZEK	O. CHASTEL

ANNEX

ORGAN AND DONOR CHARACTERISATION

PART A

Minimum data set

Minimum data – information for the characterisation of organs and donors, which has to be collected for each donation in accordance with second subparagraph of Article 7(1) and without prejudice to Article 7(2).

Minimum data set

The establishment where the procurement takes place and other general data

Type of donor

Blood group

Gender

Cause of death

Date of death

Date of birth or estimated age

Weight

Height

Past or present history of IV drug abuse

Past or present history of malignant neoplasia

Present history of other transmissible disease

HIV; HCV; HBV tests

Basic information to evaluate the function of the donated organ

PART B

Complementary data set

Complementary data – information for the characterisation of organs and donors to be collected in addition to minimum data specified in Part A, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case, in accordance with the second subparagraph of Article 7(1).

Complementary data set

General data

Contact details of the procurement organisation/the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

Donor data

Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor/organ and the recipient.

Donor medical history

Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

Physical and clinical data

Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.

Laboratory parameters

Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

Image tests

Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

Therapy

Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.

Statement of the European Parliament, the Council and the Commission on Article 290 TFEU

The European Parliament, the Council and the Commission declare that the provisions of this Directive shall be without prejudice to any future position of the institutions as regards the implementation of Article 290 TFEU or individual legislative acts containing such provisions.

Statement of the European Commission (Urgency)

The European Commission undertakes to keep the European Parliament and the Council fully informed on the possibility of a delegated act being adopted under the urgency procedure. As soon as the Commission's services foresee that a delegated act might be adopted under the urgency procedure, they will informally warn the secretariats of the European Parliament and of the Council.

IV

(Acts adopted before 1 December 2009 under the EC Treaty, the EU Treaty and the Euratom Treaty)

DECISION OF THE COUNCIL AND THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN UNION, MEETING WITHIN THE COUNCIL

of 30 November 2009

on the signing and provisional application of the Agreement on Air Transport between the European Community and its Member States, of the one part, and Canada, of the other part

(2010/417/EC)

THE COUNCIL OF THE EUROPEAN UNION AND THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES, MEETING WITHIN THE COUNCIL,

Having regard to the Treaty establishing the European Community and in particular Article 80(2), in conjunction with the first sentence of the first subparagraph of Article 300(2) thereof,

Whereas:

(1) The Commission has negotiated on behalf of the Community and of the Member States an Agreement on Air Transport with Canada (hereinafter the Agreement) in accordance with the Council Decision authorising the Commission to open negotiations.

(2) The Agreement was initialled on 30 November 2008.

(3) The Agreement negotiated by the Commission should be signed and applied provisionally by the Community and the Member States in accordance with applicable national law, subject to its possible conclusion at a later date.

(4) It is necessary to lay down appropriate procedural arrangements for the participation of the Community and the Member States in the Joint Committee set up under Article 17 of the Agreement and in the dispute settlement procedures provided in Article 21 of the Agreement, as well as for implementing certain provisions of the Agreement concerning security and safety,

HAVE DECIDED AS FOLLOWS:

Article 1

Signature

1. The signing of the Agreement on Air Transport between the European Community and its Member States, of the one part, and Canada, of the other part (hereinafter the Agreement), is hereby approved on behalf of the Community, subject to a Council Decision concerning the conclusion of the Agreement.

The text of the Agreement is attached to this Decision.

2. The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Community, subject to its conclusion.

Article 2

Provisional application

Pending its entry into force, the Agreement shall be applied on a provisional basis by the Community and its Member States, in accordance with applicable national law, from the first day of the month following the date of the latest note of which the Parties have notified each other of the completion of the relevant domestic procedures to provisionally apply the Agreement.

Article 3

Joint Committee

1. The Community and the Member States shall be represented in the Joint Committee established under Article 17 of the Agreement by representatives of the Commission and of the Member States.

2. The position to be taken by the Community and its Member States within the Joint Committee with respect to matters of exclusive Community competence that do not require the adoption of a decision having legal effect shall be established by the Commission and shall be notified in advance to the Council and the Member States.

3. For Joint Committee decisions concerning matters that fall within Community competence, the position to be taken by the Community and its Member States shall be adopted by the Council, acting by qualified majority on a proposal from the Commission, unless the applicable voting procedures set down in the Treaty establishing the European Community provide otherwise.

4. For Joint Committee decisions concerning matters that fall within Member States' competence, the position to be taken by the Community and its Member States shall be adopted by the Council, acting by unanimity, on a proposal from the Commission or from Member States, unless a Member State has informed the General Secretariat of the Council within one month of the adoption of that position that it can only consent to the decision to be taken by the Joint Committee with the agreement of its legislative bodies notably due to a parliamentary scrutiny reserve.

5. The position of the Community and of the Member States within the Joint Committee shall be presented by the Commission, except in areas that fall exclusively within Member States' competence, in which case it shall be presented by the Presidency of the Council or, if the Council so decides, by the Commission.

Article 4

Settlement of disputes

1. The Commission shall represent the Community and the Member States in dispute settlement proceedings under Article 21 of the Agreement.

2. A decision to suspend or to reinstate the application of benefits pursuant to Article 21(7) of the Agreement shall be taken by the Council on the basis of a Commission proposal. The Council shall decide by qualified majority.

3. Any other appropriate action to be taken under Article 21 of the Agreement on matters which fall within the Community competence shall be decided upon by the Commission, with the assistance of a Special Committee of representatives of the Member States appointed by the Council.

Article 5

Information to the Commission

1. Member States shall promptly inform the Commission of any decision to refuse, revoke, suspend or limit the authorisation of an airline of Canada that they intend to adopt under Article 3 of the Agreement.

2. Member States shall promptly inform the Commission of any requests or notifications made or received by them under Article 6 (Civil aviation safety) of the Agreement.

3. Member States shall promptly inform the Commission of any requests or notifications made or received by them under Article 7 (Civil aviation security) of the Agreement.

Done at Brussels, 30 November 2009.

For the Council

The President

B. ASK

AGREEMENT

on Air Transport between Canada and the European Community and its Member States

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AGREEMENT ON AIR TRANSPORT

CANADA

of the one part;

and

THE REPUBLIC OF AUSTRIA,

THE KINGDOM OF BELGIUM,

THE REPUBLIC OF BULGARIA,

THE REPUBLIC OF CYPRUS,

THE CZECH REPUBLIC,

THE KINGDOM OF DENMARK,

THE REPUBLIC OF ESTONIA,

THE REPUBLIC OF FINLAND,

THE FRENCH REPUBLIC,

THE FEDERAL REPUBLIC OF GERMANY,

THE HELLENIC REPUBLIC,

THE REPUBLIC OF HUNGARY,

IRELAND,

THE ITALIAN REPUBLIC,

THE REPUBLIC OF LATVIA,

THE REPUBLIC OF LITHUANIA,

THE GRAND DUCHY OF LUXEMBOURG,

MALTA,

THE KINGDOM OF THE NETHERLANDS,

THE REPUBLIC OF POLAND,

THE PORTUGUESE REPUBLIC,

ROMANIA,

THE SLOVAK REPUBLIC,

THE REPUBLIC OF SLOVENIA,

THE KINGDOM OF SPAIN,

THE KINGDOM OF SWEDEN,

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

being parties to the Treaty establishing the European Community and being Member States of the European Union (hereinafter the Member States),

and the EUROPEAN COMMUNITY,

of the other part;

Canada and the Member States being parties to the Convention on International Civil Aviation opened for signature at Chicago, on the 7th day of December, 1944, together with the European Community;

DESIRING to promote an aviation system based on competition among airlines in the market place with minimum government interference and regulation;

DESIRING to promote their interests in respect of air transportation;

RECOGNISING the importance of efficient air transportation in promoting trade, tourism and investment;

DESIRING to enhance air services;

DESIRING to ensure the highest degree of safety and security in air transportation;

DETERMINED to obtain the potential benefits of regulatory cooperation and, to the extent practical, harmonisation of regulations and approaches;

ACKNOWLEDGING the important potential benefits that may arise from competitive air services and viable air services industries;

DESIRING to foster a competitive air services environment, recognising that where there is not a level competitive playing field for airlines, potential benefits may not be realised;

DESIRING to make it possible for their airlines to have a fair and equal opportunity to provide the air services under this Agreement;

DESIRING to maximise benefits to passengers, shippers, airlines and airports and their employees, and others benefiting indirectly;

AFFIRMING the importance of protecting the environment in developing and implementing international aviation policy;

NOTING the importance of protecting consumers and encouraging an appropriate level of consumer protection associated with air services;

NOTING the importance of capital to the airline industry for the further development of air services;

DESIRING to conclude an agreement on air transport, supplementary to the said Convention,

HAVE AGREED AS FOLLOWS:

Article 1

Headings and definitions

1. Headings used in this Agreement are for reference purposes only.

2. For the purpose of this Agreement, unless otherwise stated:

(a) 'Aeronautical authorities' means any authority or person empowered by the Parties to perform the functions set out in this Agreement;

(b) 'Air services' means scheduled air services on the routes specified in this Agreement for the transport of passengers and cargo, including mail, separately or in combination;

(c) 'Agreement' means this Agreement, any Annex attached thereto, and any amendments to the Agreement or to any Annex;

(d) 'Airline' means an airline which has been designated and authorised in accordance with Article 3 of this Agreement;

(e) 'Party' means either Canada or the Member States and the European Community taken together or individually;

(f) 'Convention' means the Convention on International Civil Aviation opened for signature at Chicago on the seventh day of December 1944 and includes any Annex adopted under Article 90 of that Convention and any amendment of the Annexes or of the Convention under Articles 90 and 94 thereof so far as those Annexes and amendments have been adopted by Canada and the Member States; and

(g) 'Territory' means for Canada, its land areas (mainland and islands), internal waters and territorial sea as determined by its domestic law, and includes the air space above these areas; and for the Member States of the European Community, the land areas (mainland and islands), internal waters and territorial sea in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and any successor instrument, and includes the air space above these areas; the application of this Agreement to the airport of Gibraltar is understood to be without prejudice to the respective legal positions of the Kingdom of Spain and the United Kingdom with regard to the dispute over sovereignty over the territory in which the airport is situated, and to the continuing suspension of Gibraltar airport from European Community aviation measures existing as at 18 September 2006 as between Member States, in accordance with the Ministerial statement on Gibraltar airport agreed in Cordoba on 18 September 2006.

Article 2

Grant of rights

1. Each Party grants to the other Party the following rights for the conduct of air transportation by the airlines of the other Party:

(a) the right to fly across its territory without landing;

(b) the right to make stops in its territory for non-traffic purposes;

(c) to the extent permitted in this Agreement, the right to make stops in its territory on the routes specified in this Agreement for the purpose of taking up and discharging traffic in passenger and cargo, including mail, separately or in combination; and

(d) the rights otherwise specified in this Agreement.

2. Each Party also grants the rights specified in paragraphs 1(a) and (b) of this Article to the other Party for airlines of the other Party other than those referred to under Article 3 (Designation, authorisation and revocation) of this Agreement.

Article 3

Designation, authorisation and revocation

1. The Parties recognise as constituting a designation under this Agreement the licenses or other forms of authorisation issued by the other Party for the conduct of air services under this Agreement. Upon request by the aeronautical authorities of one Party, the aeronautical authorities of the other Party which issued the licence or other form of authorisation shall verify the status of such licences or authorisations.

2. On receipt of applications from a designated airline of one Party, in the form and manner prescribed, the other Party shall, consistent with its laws and regulations, grant requested authorisations and permissions to that airline to operate the air services with minimum procedural delay, provided that:

(a) such airline qualifies under the laws and regulations normally applied by the aeronautical authorities of the Party granting the authorisations and permissions;

(b) such airline complies with the laws and regulations of the Party granting the authorisations and permissions;

(c) subject to Annex 2, in the case of an airline of Canada, effective control of the airline is vested in nationals of either Party, the airline is licensed as a Canadian airline, and the airline has its principal place of business in Canada; in the case of an airline of a Member State, effective control of the airline is vested in nationals of either Party, Iceland, Liechtenstein, Norway or Switzerland, the airline is licensed as a Community airline, and the airline has its principal place of business in a Member State; and

(d) the airline otherwise operates in a manner consistent with the conditions set out in this Agreement.

3. A Party may withhold the authorisations or permissions referred to in paragraph 2 of this Article, and revoke, suspend, impose conditions or limit the operating authorisations or permissions or otherwise suspend or limit the operations of an airline or airlines of the other Party in the event of failure by that airline to comply with the provisions of paragraph 2 or where it has been determined by a Party that conditions in the territory of the other Party are not consistent with a fair and competitive environment and are resulting in a significant disadvantage or harm to its airline or airlines, pursuant to paragraph 5 of Article 14 (Competitive environment).

4. The rights enumerated in paragraph 3 of this Article shall be exercised only after consultations in the Joint Committee unless immediate action is essential to prevent infringement of the laws and regulations referred to in paragraph 2 or unless safety or security requires action in accordance with the provisions of Article 6 (Civil aviation safety) and Article 7 (Civil aviation security).

Article 4

Investment

Each Party shall permit full ownership of its airlines by nationals of Canada or a Member State or States subject to the conditions in Annex 2 to this Agreement.

Article 5

Application of laws

Each Party shall require compliance with:

(a) its laws, regulations and procedures relating to the admission to, remaining in, or departure from its territory of aircraft engaged in international air navigation, or to the operation and navigation of such aircraft, by airlines upon entrance into, departure from and while within the said territory; and

(b) its laws and regulations relating to the admission to, remaining in, or departure from its territory of passengers, crew members and cargo including mail (such as regulations relating to entry, clearance, transit, civil aviation security, immigration, passports, customs and quarantine) by airlines and by or on behalf of such passengers, crew members and cargo including mail, upon transit of, admission to, departure from and while within the said territory. In the application of such laws and regulations, each Party shall, under similar circumstances, accord to airlines treatment no less favourable than that accorded to its own or any other airline engaged in similar international air services.

Article 6

Civil aviation safety

1. The Parties reaffirm the importance of close cooperation in the field of civil aviation safety. In that context, the Parties shall engage in further cooperation including in relation to air operations, notably to allow the sharing of information which may have an impact on the safety of international air navigation, the participation in each other's oversight activities or conducting joint oversight activities in the field of civil aviation safety and the development of joint projects and initiatives, including with third countries. This cooperation shall be developed in the framework of the Agreement on Civil Aviation Safety between Canada and the European Community, done at Prague on 6 May 2009, with respect to matters covered by that Agreement.

2. Certificates of airworthiness, certificates of competency and licences, issued or rendered valid by one Party, through its aeronautical authorities, in accordance with the applicable provisions of the Agreement on Civil Aviation Safety between Canada and the European Community, shall be recognised as valid by the other Party and its aeronautical authorities for the purpose of operating the air services, provided that such certificates or licences were issued or rendered valid pursuant to, and in conformity with, as a minimum, the standards established under the Convention.

3. If the privileges or conditions of the licences or certificates referred to in paragraph 2 above, issued by the aeronautical authorities of one Party to any person or airline or in respect of an aircraft used in the operation of the air services, should permit a difference that is lower than the minimum standards established under the Convention, and which difference has been filed with the International Civil Aviation Organisation, or if those authorities should apply a standard or standards that are higher than, or other than, standards established under the Convention, the other Party may request consultations between the Parties in the framework of the Joint Committee with a view to clarifying the practice in question. Until such time as consultations may lead to a consensus and, in the spirit of a regime of reciprocal acceptance of each others' certificates and licenses, the Parties shall continue to recognise the certificates and licenses rendered valid by the aeronautical authorities of the other Party. Where the Agreement on Civil Aviation Safety between Canada and the European Community, done at Prague on 6 May 2009, has provisions governing the reciprocal acceptance of certificates and licenses, each party shall apply those provisions.

4. Consistent with applicable laws and within the framework of the Agreement on Civil Aviation Safety between Canada and the European Community, done at Prague on 6 May 2009, with respect to matters covered by that Agreement the Parties undertake to achieve reciprocal acceptance of certificates and licences.

5. A Party or its responsible aeronautical authorities may request at any time consultations with the other Party or its responsible aeronautical authorities concerning the safety standards and requirements maintained and administered by those aeronautical authorities. If, following such consultations, the Party or its responsible aeronautical authorities, which requested the consultations, find that the other Party or its responsible aeronautical authorities do not effectively maintain and administer safety standards and requirements in these areas, that, unless otherwise decided, are at least equal to the minimum standards established pursuant to the Convention, the other Party or its responsible aeronautical authorities shall be notified of such findings and the steps considered necessary to conform with these minimum standards. Failure by the other Party or its responsible aeronautical authorities to take appropriate corrective action within fifteen (15) days, or such other period as may be decided, shall constitute grounds for the Party or its responsible aeronautical authorities, which requested the consultations, to revoke, suspend or limit the operating authorisations or technical permissions or to otherwise suspend or limit the operations of an airline, the safety oversight of which is the responsibility of the other Party or its responsible aeronautical authorities.

6. Each Party accepts that any aircraft operated by or, on behalf of, an airline of one Party, may, while within the territory of the other Party, be the subject of a ramp inspection by the aeronautical authorities of the other Party, to verify the validity of the relevant aircraft documents, and those of its crew members and the apparent condition of the aircraft and its equipment, provided that such examination does not cause an unreasonable delay in operation of the aircraft.

7. If the aeronautical authorities of one Party, after carrying out a ramp inspection, find that an aircraft or the operation of an aircraft does not comply with the minimum standards established at that time pursuant to the Convention or there is a lack of effective maintenance and administration of safety standards established at that time pursuant to the Convention, the aeronautical authorities of that Party shall notify the aeronautical authorities of the other Party that are responsible for the safety oversight of the airline operating the aircraft of such findings and the steps considered necessary to conform with these minimum standards. Failure to take appropriate corrective action within fifteen (15) days shall constitute grounds for revoking, suspending or limiting the operating authorisations or technical permissions or to otherwise suspend or limit the operations of the airline operating the aircraft. The same determination may be made in the case of denial of access for ramp inspection.

8. Each Party, through its responsible aeronautical authorities, shall have the right to take immediate action including the right to revoke, suspend or limit the operating authorisations or technical permissions or otherwise suspend or limit the operations of an airline of the other Party, if they conclude that it is necessary in view of an immediate threat to civil aviation safety. Where practicable, the Party taking such measures shall endeavour to consult the other Party beforehand.

9. Any action by a Party or its responsible aeronautical authorities in accordance with paragraph 5, 7 or 8 of this Article shall be discontinued once the basis for the taking of that action ceases to exist.

Article 7

Civil aviation security

1. Consistent with their rights and obligations under international law, the Parties reaffirm that their obligation to each other to protect the security of civil aviation against acts of unlawful interference forms an integral part of this Agreement.

2. Without limiting the generality of their rights and obligations under international law, the Parties shall in particular act in conformity with the provisions of the 'Convention on offences and certain other acts committed on board aircraft', done at Tokyo on 14 September 1963, the 'Convention for the suppression of unlawful seizure of aircraft', done at The Hague on 16 December 1970, the 'Convention for the suppression of unlawful acts against the safety of civil aviation', done at Montreal on 23 September 1971, the 'Protocol for the suppression of unlawful acts of violence at airports serving international aviation', done at Montreal on 24 February 1988, and the 'Convention on the marking of plastic explosives for the purpose of detection', done at Montreal on 1 March 1991, and any other multilateral agreement governing civil aviation security binding upon the Parties.

3. The Parties shall provide upon request all necessary assistance to each other to prevent acts of unlawful seizure of civil aircraft and other acts of unlawful interference against the safety of such aircraft, their passengers and crew members, airports and air navigation facilities, and any other threat to the security of civil aviation.

4. The Parties shall act in conformity with the civil aviation security provisions established by the International Civil Aviation Organisation and designated as Annexes to the Convention on International Civil Aviation to the extent that such security provisions are applicable to the Parties. The Parties shall require that operators of aircraft of their registry, operators of aircraft who have their principal place of business or permanent residence in their territory, and the operators of airports in their territory act in conformity with such civil aviation security provisions. Accordingly, each Party, upon request, shall provide the other Party notification of any difference between its regulations and practices and the civil aviation security standards of the Annexes referred to in this paragraph, where these differences exceed or complement such standards and have relevance for the operators of the other Party. Either Party may at any time request consultations, to be held without unreasonable delay, with the other Party to discuss any such differences.

5. With full regard and mutual respect for the sovereignty of states, each Party agrees that operators of aircraft referred to in paragraph 4 of this Article may be required to observe the civil aviation security provisions referred to in that paragraph required by the other Party for entry into, departure from, or while within the territory of that other Party. Each Party shall ensure that adequate measures are effectively applied within its territory to protect the aircraft and to exercise security controls on passengers, crew members, baggage, carry-on items, cargo, mail and aircraft stores prior to boarding or loading.

6. The Parties agree to work towards achieving mutual recognition of each other's security standards and to cooperate closely on quality control measures on a reciprocal basis. The Parties also agree, where appropriate, and on the basis of decisions to be taken by Parties separately, to create preconditions for implementing one-stop security for flights between the territories of the Parties, meaning the exemption

of transfer passengers, transfer baggage, and/or transfer cargo from re-screening. To this end, they shall establish administrative arrangements allowing for consultations on existing or planned civil aviation security measures and for cooperation and for sharing of information on quality control measures implemented by the Parties. The Parties shall consult each other on planned security measures of relevance for operators located in the territory of the other Party to such administrative arrangements.

7. Each Party shall, as far as may be practicable, meet any request from the other Party for reasonable special security measures to meet a particular threat for a specific flight or a specific series of flights.

8. The Parties agree to cooperate on security inspections undertaken by them in either territory through the establishment of mechanisms, including administrative arrangements, for the reciprocal exchange of information on results of such security inspections. The Parties agree to consider positively requests to participate, as observers, in security inspections undertaken by the other Party.

9. When an incident or threat of an incident of unlawful seizure of civil aircraft or other acts of unlawful interference against the safety of such aircraft, their passengers and crew members, airports or air navigation facilities occurs, the Parties shall assist each other by facilitating communications and taking other appropriate measures intended to terminate rapidly and safely such incident or threat thereof.

10. When a Party has reasonable grounds to believe that the other Party has departed from the provisions of this Article, that Party, through its responsible authorities, may request consultations. Such consultations shall start within fifteen (15) days of receipt of such a request. Failure to reach a satisfactory agreement within fifteen (15) days from the start of consultations shall constitute grounds for the Party that requested the consultations to take action to withhold, revoke, suspend or impose appropriate conditions on the authorisations of the airlines of the other Party. When justified by an emergency, or to prevent further non-compliance with the provisions of this Article, the Party that believes that the other Party has departed from the provisions of this Article may take appropriate interim action at any time.

11. Without prejudice to the need to take immediate action in order to protect transportation security, the Parties affirm that when considering security measures, a Party shall evaluate possible adverse economic and operational effects on the operation of air services under this Agreement and, to the extent permitted by law, shall take such factors into account when it determines what measures are necessary and appropriate to address those security concerns.

Article 8

Customs duties, taxes and charges

1. Each Party shall, to the fullest extent possible under its national laws and regulations, and on the basis of reciprocity, exempt airlines of the other Party with respect to their aircraft operated in international air transport, their regular equipment, fuel, lubricants, consumable technical supplies, ground equipment, spare parts (including engines), aircraft stores (including but not limited to such items as food, beverages and liquor, tobacco and other products destined for sale to or use by passengers in limited quantities during flight), and other items intended for or used solely in connection with the operation or servicing of aircraft engaged in international air transport from all import restrictions, property taxes and capital levies, customs duties, excise taxes, and similar fees and charges that are imposed by the Parties, and not based on the cost of services provided.

2. Each Party shall also exempt, to the fullest extent possible under national laws and regulations and on the basis of reciprocity, from the taxes, levies, duties, fees and charges referred to in paragraph 1 of this Article, with the exception of charges based on the cost of the service provided:

(a) aircraft stores introduced into or supplied in the territory of a Party and taken on board, within reasonable limits, for use on outbound aircraft of an airline of the other Party engaged in international air transport, even when these stores are to be used on a part of the journey performed over the said territory;

(b) ground equipment and spare parts (including engines) introduced into the territory of a Party for the servicing, maintenance, or repair of aircraft of an airline of the other Party used in international air transport as well as computer equipment and component parts for the handling of passengers or cargo, or security checks;

(c) fuel, lubricants and consumable technical supplies introduced into or supplied in the territory of a Party for use in an aircraft of an airline of the other Party engaged in international air transport, even when these supplies are to be used on a part of the journey performed over the said territory; and

(d) printed matter, including airline tickets, ticket covers, airway bills and other related advertising materials distributed without charge by the airline.

3. The regular airborne equipment, as well as the materials and supplies normally retained on board the aircraft used by an airline of a Party, may be unloaded in the territory of the other Party only with the approval of the Customs authorities of that territory. In such case, they may be required to be placed under the supervision of the said authorities up to such time as they are re-exported or otherwise disposed of in accordance with Customs regulations.

4. The exemptions provided by this Article shall also be available where the airlines of a Party have contracted with another airline, which similarly enjoys such exemptions from the other Party, for the loan or transfer in the territory of the other Party of the items specified in paragraphs 1 and 2 of this Article.

5. The provisions of the respective conventions in force between a Member State and Canada for the avoidance of double taxation on income and on capital are not altered by this Agreement.

Article 9

Statistics

1. Each Party shall provide to the other Party statistics that are required by domestic laws and regulations, and, upon request, other available statistical information as may be reasonably required for the purpose of reviewing the operation of the air services.

2. The Parties shall cooperate in the framework of the Joint Committee to facilitate the exchange of statistical information between them for the purpose of monitoring the development of the air services.

Article 10

Consumer interests

1. Each Party recognises the importance of protecting the interests of consumers and may take or may require airlines to take, on a non-discriminatory basis, reasonable and proportionate measures concerning the following matters, including but not limited to:

(a) requirements to protect funds advanced to airlines;

(b) denied boarding compensation initiatives;

(c) passenger refunds;

(d) public disclosure of the identity of an air carrier actually operating the aircraft;

(e) financial fitness of its own airlines;

(f) passenger injury liability insurance; and

(g) setting accessibility measures.

2. The Parties endeavour to consult each other, within the framework of the Joint Committee, on matters of consumer interest, including their planned measures, with a view to achieve compatible approaches to the extent possible.

Article 11

Availability of airports and aviation facilities and services

1. Each Party shall ensure that airports, airways, air traffic control and air navigation services, civil aviation security, ground handling, and other related facilities and services that are provided in its territory shall be available for use by the airlines of the other Party on a non-discriminatory basis at the time arrangements for use are made.

2. To the fullest extent possible, Parties shall take all reasonable measures to ensure effective access to facilities and services, subject to legal, operational and physical constraints and on the basis of fair and equal opportunity, and transparency with respect to the procedures for gaining access.

3. Each Party shall ensure that its procedures, guidelines and regulations to manage slots applicable to airports in its territory are applied in a transparent, effective and non-discriminatory manner.

4. If a Party believes that the other Party is in violation of this Article, it may notify the other Party of its findings and request consultations under paragraph 4 of Article 17 (Joint Committee).

Article 12

Charges for airports and aviation facilities and services

1. Each Party shall ensure that user charges that may be imposed by its competent charging authorities or bodies on the airlines of the other Party for the use of air navigation and air traffic control services shall be just, reasonable, cost-related and not unjustly discriminatory. In any event, any such user charges shall be assessed on the airlines of the other Party on terms not less favourable than the most favourable terms available to any other airline.

2. Each Party shall ensure that user charges that may be imposed by its competent charging authorities or bodies on the airlines of the other Party for the use of airport, civil aviation security and related facilities and services shall be just, reasonable, not unjustly discriminatory, and equitably apportioned among categories of users. These charges may reflect, but shall not exceed, the full cost to the competent charging authorities or bodies of providing the appropriate airport and civil aviation security facilities and services at that airport or within that airport's system. These charges may include a reasonable return on assets, after depreciation. Facilities and services for which user charges are made shall be provided on an efficient and economic basis. In any event, these charges shall be assessed on the airlines of the other Party on terms not less favourable than the most favourable terms available to any other airline at the time the charges are assessed.

3. Each Party shall encourage consultations between the competent charging authorities or bodies in its territory and the airlines or their representative bodies using the services and facilities, and shall encourage the competent charging authorities or bodies and the airlines or their representative bodies to exchange such information as may be necessary to permit an accurate review of the reasonableness of the charges in accordance with the principles of paragraphs 1 and 2 of this Article. Each Party shall encourage the competent charging authorities to provide users with reasonable notice of any proposal for changes in user charges to enable those authorities to consider the views expressed by the users before changes are made.

4. No Party shall be held, in dispute resolution procedures pursuant to Article 21 (Settlement of disputes), to be in breach of a provision of this Article, unless:

(a) it fails to undertake a review of the charge or practice that is the subject of complaint by the other Party within a reasonable amount of time; or

(b) following such a review, it fails to take all steps within its power to remedy any charge or practice that is inconsistent with this Article.

Article 13

Commercial framework

1. Each Party shall allow a fair and equal opportunity for the airlines of the other Party to provide the air services under this Agreement.

Capacity

2. Each Party shall allow any airline of the other Party to determine the frequency and capacity of the air services it offers under this Agreement based upon the airline's commercial considerations in the market place. No Party shall unilaterally limit the volume of traffic, frequency or regularity of service, or the aircraft type or types operated by the airlines of the other Party, nor shall it require the filing of schedules, programmes for charter flights, or operations plans by airlines of the other Party, except as may be required for technical, operational or environmental (local air quality and noise) reasons under uniform conditions consistent with Article 15 of the Convention.

Codesharing

3. (a) Subject to the regulatory requirements normally applied to such operations by each Party, any airline of the other Party may enter into cooperative arrangements for the purposes of:

(i) holding out its air services on the specified routes by selling transportation under its own code on flights operated by any airline of Canada, or of Member States, and/or of any third country; and/or a surface land or marine transportation provider of any country;

(ii) carrying traffic under the code of any other airline where such other airline has been authorised by the aeronautical authorities of a Party to sell transportation under its own code on flights operated by any airline of a Party.

(b) A Party may require all airlines involved in codesharing arrangements to hold the appropriate underlying route authority.

(c) A Party shall not withhold permission for codesharing services identified in paragraph 3(a)(i) of this Article on the basis that the airline operating the aircraft does not have the right to carry traffic under the codes of other airlines.

(d) The Parties shall require all airlines in such codesharing arrangements to ensure that passengers are fully informed of the identity of the operator and the mode of transportation for each segment of the journey.

Ground handling

4. Each Party shall permit the airlines of the other Party when operating in its territory:

(a) on the basis of reciprocity, to perform their own ground handling in its territory and, at their option, to have ground handling services provided in whole or in part by any agent authorised by its competent authorities to provide such services; and

(b) to provide ground handling services for other airlines operating at the same airport, where authorised and consistent with applicable laws and regulations.

5. The exercise of the rights set forth in paragraphs 4(a) and (b) of this Article shall be subject only to physical or operational constraints resulting primarily from considerations of airport safety or security. Any constraints shall be applied uniformly and on terms no less favourable than the most favourable terms available to any airline of any country engaged in similar international air services at the time the constraints are imposed.

Airline representatives

6. Each Party shall permit:

(a) the airlines of the other Party on the basis of reciprocity, to bring into and to maintain in its territory their representatives and commercial managerial, sales, technical, operational, and other specialist staff, as required in connection with their services;

(b) these staff requirements at the option of the airlines of the other Party, to be satisfied by their own personnel or, by using the services of any other organisation, company or airline operating in its territory and authorised to perform such services for other airlines; and

(c) the airlines of the other Party to establish offices in its territory for the promotion and sale of air transportation and related activities.

7. Each Party shall require the representatives and staff of the airlines of the other Party to be subject to its laws and regulations. Consistent with such laws and regulations:

(a) each Party shall, with the minimum of delay, grant the necessary employment authorisations, visitor visas or other similar documents to the representatives and staff referred to in paragraph 6 of this Article; and

(b) each Party shall facilitate and expedite the approval of any requirement for employment authorisations for personnel performing certain temporary duties not exceeding ninety (90) days.

Sales, local expenses, and transfer of funds

8. Each Party shall permit the airlines of the other Party:

(a) to engage in the sale of air transportation in its territory directly or, at the discretion of the airlines, through their agents and to sell transportation in the currency of its territory or, at the discretion of the airlines, in freely convertible currencies of other countries, and any person shall be free to purchase such transportation in currencies accepted by those airlines;

(b) to pay local expenses, including purchases of fuel, in its territory in local currency, or at the discretion of the airlines, in freely convertible currencies; and

(c) to convert and remit abroad, on demand, funds obtained in the normal course of their operations. Such conversion and remittance shall be permitted without restrictions or delay at the foreign exchange market rates for current payments prevailing at the time of submission of the request for transfer, and shall not be subject to any charges except normal service charges collected by banks for such transactions.

Intermodal services

9. Each Party shall permit airlines operating:

(a) passenger-combination services, to employ land or maritime surface transportation in connection with the air services. Such transportation may be provided by the airlines through arrangements with surface carriers, or the airlines may elect to perform the surface transportation themselves;

(b) cargo services, to employ without restriction in connection with the air services any land or maritime surface transportation for cargo to or from any points in the territories of the Parties, or in third countries, including transport to and from all airports with customs facilities and including, where applicable, to transport cargo in bond under applicable laws and regulations; access to airport customs processing and facilities for cargo moving by surface or by air; and to elect to perform their own cargo surface transportation, subject to domestic laws and regulations governing such transportation, or to provide it through arrangements with other surface carriers, including surface transportation operated by airlines of any other country; and

(c) intermodal services, to offer, at a single through price air and surface transportation combined, provided that passengers and shippers are not misled as to the facts concerning such transportation.

Pricing

10. The Parties shall permit prices to be freely established by the airlines on the basis of free and fair competition. Neither Party shall take unilateral action against the introduction or continuation of a price for international transportation to or from its territory.

11. The Parties shall not require prices to be filed with aeronautical authorities.

12. The Parties shall permit aeronautical authorities to discuss matters such as, but not limited to, prices which may be unjust, unreasonable or discriminatory.

Computer reservation systems

13. The Parties shall apply their respective laws and regulations relating to the operations of computer reservation systems in their territories on a fair and non-discriminatory basis.

Franchising and branding

14. The airlines of any Party may provide air services under this Agreement, pursuant to a franchising or branding arrangement with companies, including airlines, provided that the airline providing the air services holds the appropriate route authority, the conditions prescribed under domestic laws and regulations are met, and subject to the approval of aeronautical authorities.

Wet leasing

15. For the purposes of providing the air services under this Agreement, provided that the airline providing the air services and the operator of the aircraft in such arrangements hold the appropriate authorities, airlines of the Parties may provide air services under this Agreement using aircraft and flight crew provided by other airlines, including from other countries, subject to the approval of aeronautical authorities. For the purposes of this paragraph, airlines operating the aircraft shall not be required to have underlying route authority.

Charter/non-scheduled flights

16. The provisions set out in Articles 4 (Investment), 5 (Application of laws), 6 (Civil aviation safety), 7 (Civil aviation security), 8 (Customs duties, taxes and charges), 9 (Statistics), 10 (Consumer interests), 11 (Availability of airports and aviation facilities and services), 12 (Charges for airports and aviation facilities and services), 13 (Commercial framework), 14 (Competitive environment), 15 (Air traffic management), 17 (Joint Committee) and 18 (Environment) of this Agreement apply as well to charters and other non-scheduled flights operated by air carriers of one Party into or from the territory of the other Party.

17. When granting requested authorisations and permissions to an air carrier on receipt of applications to operate charters and other non-scheduled flights, the Parties shall act with minimum procedural delay.

Article 14

Competitive environment

1. The Parties acknowledge that it is their joint objective to have a fair and competitive environment for the operation of the air services. The Parties recognise that fair competitive practices by airlines are most likely to occur where these airlines operate on a fully commercial basis and are not state subsidised. They recognise that matters, such as, but not limited to the conditions under which airlines are privatised, the removal of competition distorting subsidies, equitable and non-discriminatory access to airport facilities and services and to computer reservation systems are key factors to achieve a fair and competitive environment.

2. If a Party finds that conditions exist in the territory of the other Party that would adversely affect a fair and competitive environment and its airlines' operation of the air services under this Agreement, it may submit observations to the other Party. Furthermore, it may request a meeting of the Joint Committee. The Parties accept that the degree to which the objectives in the Agreement related to a competitive environment may be undermined by a subsidy or other intervention is a legitimate subject for discussion in the Joint Committee.

3. Issues that may be raised under this Article 14 include, but are not limited to, capital injections, cross subsidisation, grants, guarantees, ownership, tax relief or tax exemption, protection against bankruptcy or insurance by any government entities. Subject to paragraph 4 of Article 14, a Party, upon notification to the other Party, may approach responsible government entities in the territory of the other Party including entities at the state, provincial or local level to discuss matters relating to this Article.

4. The Parties recognise the cooperation between their respective competition authorities as evidenced by the Agreement between the Government of Canada and the European Communities regarding the Application of their competition laws, done at Bonn on 17 June 1999.

5. If, following consultations in the Joint Committee, a Party believes that the conditions referred to in paragraph 2 of Article 14 persist and are likely to result in significant disadvantage or harm being caused to its airline or airlines, it may take action. A Party may take action under this paragraph from the earlier of the establishment, by a decision of the Joint Committee, of procedures and criteria by the Joint Committee for the exercise of such action or one year from the date that this Agreement is applied provisionally by the Parties or enters into force. Any action taken pursuant to this paragraph shall be appropriate, proportionate and restricted with regard to scope and duration to what is strictly necessary. It shall be exclusively directed towards the entity benefiting from the conditions referred to in paragraph 2, and shall be without prejudice to the right of any Party to take action under Article 21 (Settlement of disputes).

Article 15

Air traffic management

The Parties shall cooperate on addressing safety oversight and policy issues relating to air traffic management, with a view to optimising overall efficiency, reducing cost, and enhancing the safety and capacity of existing systems. The Parties shall encourage their air navigation service providers to continue to collaborate on interoperability to further integrate both sides' systems where possible, to reduce the environmental impact of aviation, and to share information where appropriate.

Article 16

Continuation of designations and authorisations

1. Any airline of Canada or of a Member State holding a current designation from its respective government under an air transport agreement with Canada superseded by this Agreement shall be deemed to be an airline designated to conduct air services.

2. Any airline of Canada or of a Member State holding a licence or authorisation issued by the aeronautical authorities of a Party valid for the operation of air services on the date of entry into force of this Agreement shall, pending issuance of any new or amended licence or authorisation under this Agreement, continue to have all the authorities provided in the said licence or authorisation and be deemed to have therein the authority to operate air services as provided for in this Agreement.

3. Nothing in this Article shall prevent an airline of a Party not referred to in paragraph 1 or 2 of this Article from being designated or authorised to conduct air services.

Article 17

Joint Committee

1. The Parties hereby establish a committee composed of representatives of the Parties (hereinafter referred to as the Joint Committee).

2. The Joint Committee shall identify aeronautical authorities and other competent authorities for matters covered under this Agreement and facilitate contacts between them.

3. The Joint Committee shall meet as and when necessary and at least once a year. Either Party may request the convening of a meeting.

4. A Party may also request a meeting of the Joint Committee to consult regarding any question relating to the interpretation or application of this Agreement and to seek to resolve any concerns raised by the other Party. Such a meeting shall begin at the earliest possible date, but not later than two months from the date of receipt of the request, unless the Parties decide otherwise.

5. The Joint Committee shall adopt decisions where expressly provided by the Agreement.

6. The Joint Committee shall foster cooperation between the Parties and may consider any matter related to the operation or implementation of this Agreement, including, but not limited to:

(a) reviewing market conditions affecting air services under this Agreement;

(b) exchanging information, including advising as to changes to domestic law and policies, which affect the Agreement;

(c) considering potential areas for the further development of the Agreement, including the recommendation of amendments to the Agreement;

(d) recommending conditions, procedures, and amendments required for new Member States to become Parties to this Agreement; and

(e) discussing issues related to investment, ownership and control, and confirming when the conditions for the progressive opening of traffic rights as set out in Annex 2 to this Agreement are met.

7. The Joint Committee shall develop cooperation and foster expert-level exchanges on new legislative or regulatory initiatives.

8. The Joint Committee shall adopt, by decision, its rules of procedure.

9. All decisions of the Joint Committee shall be made by consensus.

Article 18

Environment

1. The Parties recognise the importance of protecting the environment when developing and implementing international aviation policy.

2. Without prejudice to the rights and obligations of the Parties under international law and the Convention, each Party within its own sovereign jurisdiction shall have the right to take and apply the appropriate measures to address the environmental impacts of air transport provided that such measures are applied without distinction as to nationality.

3. The Parties recognise that the costs and benefits of measures to protect the environment must be carefully weighed in developing international aviation policy. When a Party is considering proposed environmental measures, it should evaluate possible adverse effects on the exercise of rights contained in this Agreement, and, if such measures are adopted, it should take appropriate steps to mitigate any such adverse effects.

4. The Parties recognise the importance of working together, and within the framework of multilateral discussions, to consider the effects of aviation on the environment and the economy, and to ensure that any mitigating measures are fully consistent with the objectives of this Agreement.

5. When environmental measures are established, the aviation environmental standards adopted by the International Civil Aviation Organisation in Annexes to the Convention shall be followed except where differences have been filed.

6. The Parties shall endeavour to consult each other on matters of the environment, including on planned measures likely to have a significant effect on the international air services covered by this Agreement, with a view to achieve compatible approaches to the extent possible. Consultations shall start within 30 days of receipt of such a request, or any other period of time where mutually determined.

Article 19

Labour matters

1. The Parties recognise the importance of considering the effects of this Agreement on labour, employment and working conditions.

2. Either Party may request a meeting of the Joint Committee under Article 17 in order to discuss the labour matters referred to in paragraph 1 of this Article.

Article 20

International cooperation

The Parties may bring to the Joint Committee under Article 17 issues related to:

(a) air transport and international organisations;

(b) possible developments in relations between the Parties and other countries in air transport; and

(c) trends in bilateral or multilateral arrangements;

including, where possible, proposals on the development of coordinated positions in these fields.

Article 21

Settlement of disputes

1. If any dispute arises between the Parties relating to the interpretation or application of this Agreement they shall in the first place endeavour to settle it through formal consultations within the Joint Committee. Such formal consultations shall begin as soon as possible and notwithstanding paragraph 4 of Article 17 within a period of no more than 30 days from the date of receipt by one Party of the written request made by the other Party, referring to this Article, unless otherwise decided by the Parties.

2. If the dispute is not resolved within 60 days of the receipt of the request for formal consultations, it may be referred to a person or body for decision by consent of the Parties. If the Parties do not so consent, the dispute shall, at the request of either Party be submitted to arbitration by a tribunal of three arbitrators in accordance with the procedures set forth below.

3. Within 30 days from the receipt of a request for arbitration each Party to the dispute shall nominate an independent arbitrator. The third arbitrator shall be appointed within a further period of 45 days by agreement between the two arbitrators named by the Parties. If either of the Parties fails to nominate an arbitrator within the period specified, or if the third arbitrator is not appointed within the period specified, the President of the Council of the International Civil Aviation Organisation may be requested by either Party to appoint an arbitrator or arbitrators as the case requires. If the President is of the same nationality as one of the Parties, the most senior Vice-president who is not disqualified on that ground shall make the appointment. In all cases the third arbitrator shall be a national of a third State, shall act as President of the Tribunal and shall determine the place where arbitration will be held.

4. The Tribunal shall establish its own rules of procedure and the timetable for the proceedings.

5. At the request of a Party the Tribunal may order the other Party to the dispute to implement interim relief measures pending the Tribunal's final determination.

6. The Tribunal shall attempt to render a written decision within 180 days from the receipt of the request for arbitration. The decision of the majority of the Tribunal shall prevail.

7. If the Tribunal determines that there has been a violation of this Agreement and the responsible Party does not cure the violation, or does not reach a resolution with the other Party to the dispute on a mutually satisfactory solution within 30 days after notification of the Tribunal's decision, the other Party may suspend the application of equivalent benefits arising under this Agreement until such time as the dispute has been resolved.

8. The expenses of the Tribunal shall be shared equally between the Parties to the dispute.

9. For the purposes of this Article, the European Community and the Member States shall act together.

Article 22

Amendment

Any amendment to this Agreement may be mutually determined by the Parties pursuant to consultations held in conformity with Article 17 (Joint Committee) of this Agreement. Amendments shall come into force in accordance with the terms set out in Article 23 (Entry into force and provisional application).

Article 23

Entry into force and provisional application

1. This Agreement shall enter into force one month after the date of the latest diplomatic note in which the Parties confirm that all necessary procedures for the entry into force of this Agreement have been completed. For purposes of this exchange, the European Community and its Member States nominate the General Secretariat of the Council of the European Union. Canada shall deliver to the General Secretariat of the Council of the European Union the diplomatic note(s) to the European Community and its Member States, and the General Secretariat of the Council of the European Union shall deliver to Canada the diplomatic notes from the European Community and its Member States. The diplomatic note or notes from the European Community and its Member States shall contain communications from each Member State confirming that its necessary procedures for entry into force of this Agreement have been completed.

2. Notwithstanding paragraph 1 of this Article, the Parties agree to provisionally apply this Agreement in accordance with the provisions of domestic law of the Parties from the first day of the month following the date of the latest note by which the Parties have notified each other of the completion of the relevant domestic procedures to provisionally apply this Agreement.

Article 24

Termination

A Party may at any time give notice in writing through diplomatic channels to the other Party of its decision to terminate this Agreement. Such notice shall be communicated simultaneously to the International Civil Aviation Organisation and the United Nations Secretariat. The Agreement shall terminate one (1) year after the date of receipt of the notice by the other Party, unless the notice to terminate is withdrawn by mutual consent before the expiry of this period. In the absence of an acknowledgement of receipt by the other Party, the notice shall be deemed to have been received fourteen (14) days after the receipt of the notice by the International Civil Aviation Organisation and the United Nations Secretariat.

Article 25

Registration of the Agreement

This Agreement and any amendment thereto shall be registered with the International Civil Aviation Organisation and the United Nations Secretariat, in accordance with Article 102 of the Charter of the United Nations, following its entry into force. The other Party shall be informed of registration as soon as this has been confirmed by the Secretariats of the International Civil Aviation Organisation and the United Nations.

Article 26

Relationship to other agreements

1. If the Parties become parties to a multilateral agreement, or endorse a decision adopted by the International Civil Aviation Organisation or another international intergovernmental organisation, that addresses matters covered by this Agreement, they shall consult in the Joint Committee to determine the extent to which this Agreement is affected by the provisions of the multilateral agreement or decision and whether this Agreement should be revised to take into account such developments.

2. During the period of provisional application pursuant to paragraph 2 of Article 23 (Entry into force and provisional application) of the Agreement, the bilateral agreements listed in Annex 3 to this Agreement shall be suspended except to the extent provided in Annex 2 to this Agreement. Upon entry into force pursuant to paragraph 1 of Article 23 of this Agreement, this Agreement shall supersede the relevant provisions of the bilateral agreements listed in Annex 3 to this Agreement except to the extent provided in Annex 2 to this Agreement.

IN WITNESS WHEREOF, the undersigned, duly authorised thereto, have signed this Agreement.

DONE in duplicate at Brussels on this seventeenth day of December 2009 in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish, Swedish languages, each version being equally authentic.

Voor het Koninkrijk België

Pour le Royaume de Belgique

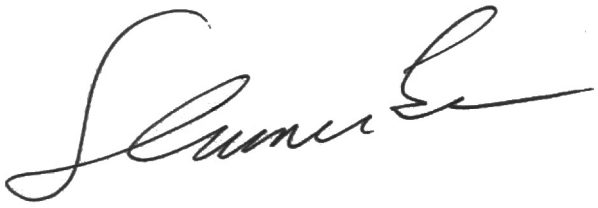
Für das Königreich Belgien

Deze handtekening verbindt eveneens het Vlaamse Gewest, het Waalse Gewest en het Brussels Hoofdstedelijk Gewest.

Cette signature engage également la Région wallonne, la Région flamande et la Région de Bruxelles-Capitale.

За Република България

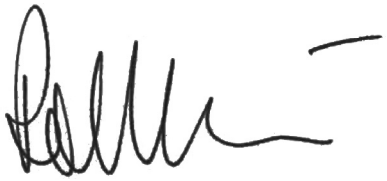
Za Českou republiku



På Kongeriget Danmarks vegne

Für die Bundesrepublik Deutschland

Eesti Vabariigi nimel



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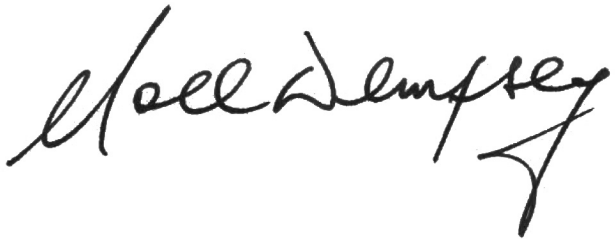

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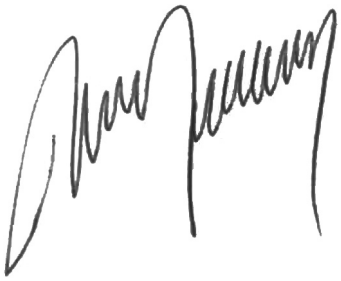


Por el Reino de España

Pour la République française

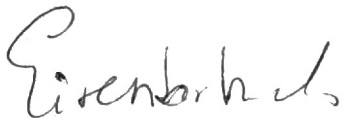
Per la Repubblica italiana

Για την Κυπριακή Δημοκρατία

Latvijas Republikas vārdā

Lietuvos Respublikos vardu

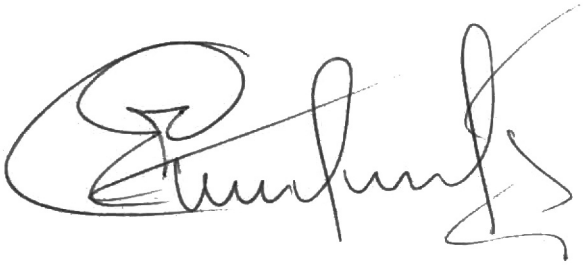
Pour le Grande-Duché de Luxembourg



A Magyar Köztársaság részéről

Ghal Malta

Voor het Koninkrijk der Nederlanden



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W imieniu Rzeczypospolitej Polskiej

Pela República Portuguesa

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Za Republiko Slovenijo

Za Slovenskú republiku

Suomen tasavallan puolesta

För Republiken Finland

För Konungariket Sverige

For the United Kingdom of Great Britain and Northern Ireland

За Европейската общност
Por la Comunidad Europea
Za Evropské společenství
For Det Europæiske Fællesskab
Für die Europäische Gemeinschaft
Euroopa Ühenduse nimel
Για την Ευρωπαϊκή Κοινότητα
For the European Community
Pour la Communauté européenne
Per la Comunità europea
Eiropas Kopienas vārdā
Europos bendrijos vardu
az Európai Közösség részéről
Għall-Komunità Ewropea
Voor de Europese Gemeenschap
W imieniu Wspólnoty Europejskiej
Pela Comunidade Europeia
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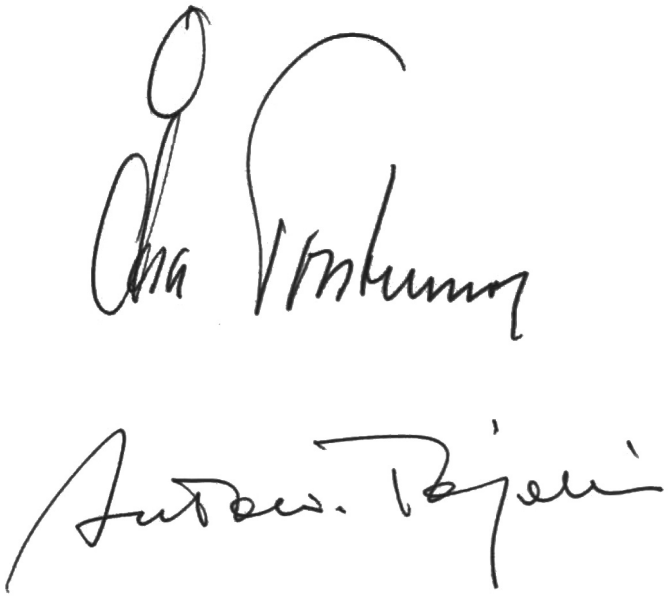
Za Evropsko skupnost
Euroopan yhteisön puolesta
På Europeiska gemenskapens vägnar



For Canada
Pour le Canada

ANNEX 1

ROUTE SCHEDULE

1. For the purposes of paragraph 1(c) of Article 2 of this Agreement each Party shall permit the airlines of the other Party to provide transportation on the routes specified hereunder:

   (a) For the airlines of Canada:

   Points Behind — Points in Canada — Intermediate Points — Points in and within Member States — Points Beyond

   (b) For the airlines of the European Community:

   Points Behind — Points in Member States — Intermediate Points — Points in and within Canada — Points Beyond

2. Airlines of a Party may on any or all flights and at their option:

   (a) operate flights in either or both directions;

   (b) combine different flight numbers within one aircraft operation;

   (c) serve behind, intermediate and beyond points and points in the territory of any Party and in any combination or any order;

   (d) omit stops at any point or points;

   (e) transfer traffic from any of its aircraft to any of its other aircraft without any limitation as to change in type or number of aircraft operated at any point;

   (f) serve points behind any point in that Party's territory with or without change of aircraft or flight number and hold out and advertise such services to the public as through services;

   (g) make stopovers at any points whether within or outside the territory of either Party;

   (h) carry transit traffic at intermediate points and at points in the territory of the other Party;

   (i) combine traffic on the same aircraft regardless of where such traffic originates; and

   (j) provide service through codesharing consistent with paragraph 3 of Article 13 (Commercial framework) of this Agreement;

   without directional or geographic limitation and without loss of any right to carry traffic otherwise permissible under this Agreement.

ANNEX 2

ARRANGEMENTS FOR THE AVAILABILITY OF RIGHTS

SECTION 1

Ownership and control of the airlines of both Parties

1. Notwithstanding Article 4 (Investment), ownership of a Party's airlines by nationals of all other Parties shall be allowable, on the basis of reciprocity, to the extent permitted by Canada's domestic laws and regulations for foreign investment in airlines.

2. Notwithstanding paragraph 2(c) of Article 3 (Designation, authorisation and revocation) and Article 4 (Investment) of the Agreement, the following provision shall apply with respect to ownership and control of airlines in place of paragraph 2(c) of Article 3 (Designation, authorisation and revocation) until the laws and regulations referred to in paragraphs 2(c) and (d) of Section 2 of this Annex dictate otherwise:

'in the case of an airline of Canada, substantial ownership and effective control of the airline are vested in nationals of Canada, the airline is licensed as a Canadian airline, and the airline has its principal place of business in Canada; in the case of an airline of a Member State, substantial ownership and effective control of the airline is vested in nationals of Member States, Iceland, Liechtenstein, Norway or Switzerland, the airline is licensed as a Community airline, and the airline has its principal place of business in a Member State'.

SECTION 2

Progressive availability of traffic rights

1. When exercising the traffic rights set out in paragraph 2 of this Section, the airlines of the Parties shall enjoy the operational flexibilities permitted in paragraph 2 of Annex 1.

2. Notwithstanding the traffic rights set out in Annex 1 to this Agreement:

(a) when the national laws and regulations of both Parties permit nationals of the other Party to own and control up to a total of 25 per cent of the voting interests of their airlines, the following rights shall apply:

(i) for passenger-combination and all-cargo services, for Canadian airlines, the right to provide international transportation between any points in Canada and any points in Member States; for Community airlines, the right to provide air services between any points in Member States and any points in Canada. In addition, for passenger-combination and all-cargo services, for airlines of a Party, the right to provide international transportation to and from points in third countries via any points in the territory of that Party with or without change of aircraft or flight number and hold out and advertise such services to the public as through services;

(ii) for all-cargo services, for airlines of both Parties, the right to provide international transportation between the territory of the other Party and points in third countries in conjunction with services between points in its territory and points in the territory of the other Party;

(iii) for passenger-combination and all-cargo services, for airlines of both Parties, operating rights that are provided for in bilateral air transport agreements between Canada and Member States listed in Section 1 of Annex 3, and the operating rights in arrangements that were being applied between Canada and individual Member States, as specified in Section 2 of Annex 3. With respect to beyond fifth freedom rights specified in this subparagraph, all limitations other than geographic limitations, limitations as to the number of points and specified frequency limitations shall no longer apply; and

(iv) for greater certainty, the rights contained in subparagraphs (i) and (ii) above shall be available where no bilateral agreement or arrangement existed on the date of provisional application or entry into force of this Agreement, or where the rights in an agreement that were available immediately prior to provisional application or entry into force of this Agreement are not as liberal as the rights contained in subparagraphs (i) and (ii) above;

(b) when the national laws and regulations of both Parties permit nationals of the other Party to own and control up to a total of 49 per cent of the voting interests of their airlines, the following rights additional to subparagraph 2(a) shall apply:

(i) for passenger-combination services, for the airlines of both Parties, fifth freedom rights shall be available at any intermediate points, and for Canadian airlines, between any points in Member States and any points in other Member States, provided that in the case of Canadian airlines the service includes a point in Canada, and in the case of Community airlines the service includes a point in any Member State;

(ii) for passenger-combination services, for the airlines of Canada, fifth freedom rights shall be available between any points in Member States and any points in Morocco, Switzerland, the European Economic Area, and other members of the European Common Aviation Area; and

(iii) for all-cargo services, for the airlines of a Party, without a requirement to serve a point in the territory of that Party, the right to provide international transportation between points in the territory of the other Party and points in third countries;

(c) when the national laws and regulations of both Parties permit the nationals of the other Party to establish an airline in their territory for domestic and international air services, and pursuant to paragraphs 5, 6(e) and 9 of Article 17 (Joint Committee) of this Agreement, the following rights additional to subparagraphs 2(a) and (b) shall apply:

(i) for passenger-combination services, for airlines of both Parties, fifth freedom rights shall be available to any points beyond without frequency limitations;

(d) when the national laws and regulations of both Parties permit the full ownership and control of their airlines by nationals of the other Party and both Parties permit full application of Annex 1, pursuant to paragraphs 5, 6(e) and 9 of Article 17 (Joint Committee) of this Agreement and pursuant to a confirmation by the Parties through their respective procedures, the provisions of Annex 2 above shall no longer apply and Annex 1 shall take effect.

ANNEX 3

BILATERAL AGREEMENTS BETWEEN CANADA AND THE MEMBER STATES OF THE EUROPEAN COMMUNITY

SECTION 1

As provided in Article 26 of this Agreement, the following bilateral agreements between Canada and the Member States shall be suspended or superseded by this Agreement:

(a) The Republic of Austria: Agreement between the Government of Canada and the Austrian Federal Government on Air Transport, signed 22 June 1993;

(b) The Kingdom of Belgium: Agreement between the Government of Canada and the Government of Belgium on Air Transport, signed 13 May 1986;

(c) The Czech Republic: Agreement between the Government of Canada and the Government of the Czech Republic on Air Transport, signed 13 March 1996; Exchange of Notes amending the Agreement, signed 28 April 2004 and 28 June 2004;

(d) The Kingdom of Denmark: Agreement between Canada and Denmark for Air Services between the Two Countries, signed 13 December 1949; Exchange of Notes between Canada and Denmark relating to the Air Agreement signed between the two Countries at Ottawa, 13 December 1949, signed 13 December 1949; Exchange of Notes between Canada and Denmark modifying the Agreement of 1949 Concerning Air Services, signed 16 May 1958;

(e) The Republic of Finland: Agreement between the Government of Canada and the Government of Finland for Air Services between and beyond their Respective Territories, signed 28 May 1990. Exchange of Notes constituting an Agreement amending the Agreement between the Government of Canada and the Government of Finland for Air Services between and beyond their Respective Territories, done at Helsinki on 28 May 1990, signed 1 September 1999;

(f) The French Republic: Air Transport Agreement between the Government of Canada and the Government of the French Republic, signed 15 June 1976 Exchange of Notes between the Government of Canada and the Government of the French Republic amending the Air Transport Agreement signed in Paris 15 June 1976, signed 21 December 1982;

(g) The Federal Republic of Germany: Air Transport Agreement between the Government of Canada and the Government of the Federal Republic of Germany, signed 26 March 1973; Exchange of Notes between the Government of Canada and the Government of the Federal Republic of Germany amending the Air Transport Agreement signed at Ottawa on 26 March 1973, signed 16 December 1982 and 20 January 1983;

(h) The Hellenic Republic: Agreement between the Government of Canada and the Government of the Hellenic Republic on Air Transport, signed 20 August 1984; Exchange of Notes constituting an Agreement between the Government of Canada and the Government of the Hellenic Republic amending the Agreement on Air Transport, done at Toronto on 20 August 1984, signed 23 June 1995 and 19 July 1995;

(i) The Republic of Hungary: Agreement between the Government of Canada and the Government of the Republic of Hungary on Air Transport, signed 7 December 1998;

(j) Ireland: Agreement between Canada and Ireland for Air Services between the two countries, signed 8 August 1947; Exchange of Notes (19 April and 31 May 1948) between Canada and Ireland amending the Agreement for Air Services between the two countries, signed 31 May 1948; Exchange of Notes between Canada and Ireland constituting an Agreement amending the Annex to the Air Agreement of 8 August 1947, signed 9 July 1951. Exchange of Notes between Canada and Ireland modifying the Air Agreement of 8 August 1947 between the two countries, signed 23 December 1957;

(k) The Italian Republic: Agreement between Canada and Italy for Air Services, signed 2 February 1960; Exchange of Notes between the Government of Canada and the Government of the Republic of Italy constituting an Agreement to Amend the Agreement for Air Services as specified in the Agreed Minute of April 28, 1972, signed 28 August 1972;

(l) The Kingdom of the Netherlands: Agreement between the Government of Canada and the Government of the Kingdom of the Netherlands relating to Air Transport, signed 2 June 1989; Exchange of Notes between the Government of Canada and the Government of the Kingdom of the Netherlands constituting an Agreement relating to the Operation of Non-scheduled (charter) Flights, signed 2 June 1989;

(m) The Republic of Poland: Air Transport Agreement between the Government of Canada and the Government of the Polish People's Republic, signed 14 May 1976; Exchange of Notes constituting an agreement between the Government of Canada and the Government of the Polish People's Republic relating to Articles IX, XI, XIII and XV of the Air Transport Agreement signed 14 May 1976, signed at the same date;

(n) The Portuguese Republic: Agreement between the Government of Canada and the Government of Portugal for Air Services between Canadian and Portuguese Territories, signed 25 April 1947; Exchange of Notes between the Government of Canada and the Government of Portugal amending paragraphs 3 and 4 of the Annex to the Agreement for Air Services between the two countries signed at Lisbon 25 April 1947, signed 24 and 30 April 1957. Exchange of Notes between Canada and Portugal amending paragraph 7 of the Annex to the Agreement for Air Services between the two countries, signed 5 and 31 March 1958;

(o) Romania: Agreement between the Government of Canada and the Government of the Socialist Republic of Romania on Civil Air Transport, signed 27 October 1983;

(p) The Kingdom of Spain: Agreement between the Government of Canada and the Government of Spain on Air Transport, signed 15 September 1988;

(q) The Kingdom of Sweden: Agreement between Canada and Sweden for Air Services between Canadian and Swedish Territories, signed 27 June 1947; Exchange of Notes between Canada and Sweden supplementing the Agreement for Air Services between Canadian and Swedish Territories, signed 27 June and 28 June 1947. Exchange of Notes between Canada and Sweden modifying the Agreement of 1947 concerning air services, signed 16 May 1958; and

(r) The United Kingdom of Great Britain and Northern Ireland: Agreement between the Government of Canada and the Government of the United Kingdom of Great Britain and Northern Ireland Concerning Air Services, signed 22 June 1988.

SECTION 2

For the purposes of Annex 2, Section 2, the following rights shall be available in accordance with subparagraph 2(a)(iii):

Part 1 for the Airlines of Canada

In conjunction with the operation of passenger-combination services between Canada and individual Member States, and in the operation of all-cargo services, airlines of Canada shall enjoy the following rights:

Member State	Traffic rights
Bulgaria	Fifth freedom rights shall be available at two points to be named which may be served intermediate to and/or beyond Sofia.
Czech Republic	Fifth freedom rights shall be available at up to four points of Canada's choice, intermediate to or beyond Prague and one additional point in the Czech Republic.
Denmark	Fifth freedom rights shall be available between Copenhagen and: (a) Amsterdam and Helsinki; or (b) Amsterdam and Moscow. Amsterdam may be served as an intermediate point or as a point beyond. Helsinki and Moscow are to be served as points beyond.
Germany	Fifth freedom traffic rights may be exercised between intermediate points in Europe and points in Federal Republic of Germany and between points in the Federal Republic of Germany and points beyond.
Greece	Fifth freedom rights shall be available at points intermediate to and/or beyond Athens and two additional points in Greece, excluding points in Turkey and Israel. The total number of intermediate points and points beyond that may be served at any one time with fifth freedom rights shall not exceed five of which no more than four may be intermediate points.
Ireland	Fifth freedom rights shall be available between points in Ireland and intermediate points, and between points in Ireland and points beyond Ireland. For all-cargo services, the right shall be available to provide international transportation between points in Ireland and points in third countries without a requirement to serve a point in Canada.

Member State	Traffic rights
Italy	Fifth freedom traffic rights shall be available between two intermediate points in Europe and Rome and/or Milan. Intermediate points with fifth freedom rights may also be served as points beyond.
Poland	Fifth freedom rights shall be available between Warsaw and two intermediate points in Europe to be selected by Canada from the following: Brussels, Copenhagen, Prague, Shannon, Stockholm, Vienna, Zurich.
Portugal	Fifth freedom traffic rights shall be available between points in Portugal and intermediate points, and between points in Portugal and points beyond Portugal.
Spain	Intermediate and beyond fifth freedom rights shall be available: (a) between Madrid and three additional points in Spain, and points in Europe, (except for Munich, Denmark, Sweden, Norway, Italy and the Republics of the former USSR); and (b) between Madrid and one other point in Spain and points in Africa and the Middle East, as defined by ICAO in Document 9060-AT/723. Not more than four fifth freedom rights shall be exercised at any one time.
Sweden	Fifth freedom rights shall be available between Stockholm and: (a) Amsterdam and Helsinki; or (b) Amsterdam and Moscow. Amsterdam may be served as an intermediate point or as a point beyond. Helsinki and Moscow are to be served as points beyond.
United Kingdom	Fifth freedom rights shall be available between points in the United Kingdom and intermediate points, and between points in the United Kingdom and points beyond. For all-cargo services, the right shall be available to provide international transportation between points in the United Kingdom and points in third countries without a requirement to serve a point in Canada.

Part 2 for the Airlines of the European Community

In conjunction with the operation of passenger-combination services between individual Member States and Canada, and in the operation of all-cargo services, Community airlines shall enjoy the following rights:

Member State	Traffic rights
Belgium	Fifth freedom traffic rights shall be available between Montreal and two points beyond in the United States of America located east of and including Chicago and north of and including Washington DC.
Bulgaria	Fifth freedom rights may be exercised at one beyond point in the United States of America east of and excluding Chicago and north of and including Washington DC. No fifth freedom rights shall be available if Montreal and Ottawa are co-terminalled. No fifth freedom rights shall be available at intermediate points.
Czech Republic	Fifth freedom rights shall be available between Montreal and two beyond points in the United States of America, north of and including Washington DC and east of and including Chicago.
Denmark	Fifth freedom rights shall be available between Montreal and Chicago and between Montreal and Seattle. Chicago may be served as an intermediate point or as a point beyond. Seattle may only be served as a point beyond.
Germany	Fifth freedom traffic rights shall only be available between Montreal and one beyond point in Florida. As an alternative, fifth freedom traffic rights shall be available between Montreal and two beyond points in the Continental United States of America excluding points in the states of California, Colorado, Florida, Georgia, Oregon, Texas and Washington.
Greece	Fifth freedom traffic rights shall be available between Montreal and Boston or between Montreal and Chicago or beyond Toronto to one point to be named by the Hellenic Republic in the United States of America, with the exception of points in California, Texas and Florida.

Member State	Traffic rights
Ireland	Fifth freedom rights shall be available between points in Canada and intermediate points, and between points in Canada and points beyond Canada. For all-cargo services, the right shall be available to provide international transportation between points in Canada and points in third countries without a requirement to serve a point in Ireland.
Italy	Fifth freedom traffic rights shall be available between two intermediate points in the northeast United States of America (north of and including Washington; east of and including Chicago) and Montreal and/or Toronto. Intermediate points with fifth freedom rights may also be served as points beyond.
Poland	Fifth freedom rights shall be available between Montreal and New York as an intermediate or beyond point.
Portugal	Fifth freedom traffic rights shall be available between points in Canada and intermediate points, and between points in Canada and points beyond.
Spain	Intermediate and beyond fifth freedom rights shall be available: (a) between Montreal and three additional points in Canada, and Chicago, Boston, Philadelphia, Baltimore, Atlanta, Dallas/Ft. Worth and Houston; and (b) between Montreal and Mexico City. Not more than four fifth freedom rights shall be exercised at any one time.
Sweden	Fifth freedom rights shall be available between Montreal and Chicago and between Montreal and Seattle. Chicago may be served as an intermediate point or as a point beyond. Seattle may only be served as a point beyond.
United Kingdom	Fifth freedom rights shall be available between points in Canada and intermediate points and between points in Canada and points beyond Canada. For all-cargo services, the right shall be available to provide international transportation between points in Canada and points in third countries without a requirement to serve a point in the United Kingdom.

SECTION 3

Notwithstanding Section 1 of this Annex, for areas that are not included within the definition of 'Territory' in Article 1 of this Agreement, the agreements in paragraphs (d) The Kingdom of Denmark, (f) The French Republic, (l) The Kingdom of the Netherlands, and (r) The United Kingdom of Great Britain and Northern Ireland shall continue to apply, according to their terms.

Declaration by the European Community and its Member States on the EU-Canada Air Transport Agreement to be made at the signature

'With regard to Article 26(2), the European Community and its Member States confirm that the phrase "the bilateral agreements in force listed in Annex 3 shall be suspended except to the extent provided for in Annex 2" has the same effect as stating that the relevant provisions in the Agreement shall prevail over the relevant provisions of the bilateral agreements in force listed in Annex 3.'

Declaration by the European Community and its Member States on the EU-Canada Air Transport Agreement to be made at the signature

'The European Community and its Member States clarify that the Air Transport Agreement between the European Community and its Member States on the one part, and Canada, on the other part, in particular in its Article 8, does not provide for the exemption from value added tax (VAT), with the exception of turnover tax on imports, and does not preclude Member States from taxing aviation fuel for domestic or intra-Community flights in line with Council Directive 2003/96/EC.'

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