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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.

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

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

of 24 June 2010

on the signing and provisional application of the Protocol to Amend the Air Transport Agreement between the United States of America, of the one part, and the European Community and its Member States, of the other part

(2010/465/EU)

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 on the Functioning of the European Union and in particular Article 100(2), in conjunction with Article 218(5) and the first subparagraph of Article 218(8) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Air Transport Agreement between the United States of America, of the one part, and the European Community and its Member States, of the other part, signed on 25 and 30 April 2007 (hereinafter, the 'Agreement'), included an obligation on both Parties to enter into second stage negotiations.

(2) As a consequence of the entry into force of the Treaty of Lisbon on 1 December 2009, the European Union has replaced and succeeded the European Community.

(3) The Commission has negotiated on behalf of the Union and of the Member States a protocol to amend the Agreement (hereinafter, the 'Protocol') in accordance with Article 21 of that Agreement.

(4) The Protocol was initialled on 25 March 2010.

(5) The Protocol is fully consistent with the Union legislation, particularly with the EU Emissions Trading System.

(6) The Protocol negotiated by the Commission should be signed and applied provisionally by the Union and the Member States, to the extent permitted under domestic law, subject to its possible conclusion at a later date.

(7) It is necessary to lay down procedural arrangements for deciding, if appropriate, how to discontinue the provisional application of the Protocol and how to take measures pursuant to Article 21(5) of the Agreement as amended by the Protocol. It is also necessary to lay down procedural arrangements for the suspension of the reciprocal recognition of regulatory determinations with regard to airline fitness and citizenship pursuant to Article 6 *bis*(2) of the Agreement as amended by the Protocol and for implementing certain provisions of the Agreement, including those concerning the environment pursuant to Article 15(5) of the Agreement as amended by the Protocol,

HAVE ADOPTED THIS DECISION:

Article 1

Signing and provisional application

1. The signing of the Protocol to Amend the Air Transport Agreement between the United States of America, of the one part, and the European Community and its Member States, of the other part (hereinafter the 'Protocol') is hereby approved on behalf of the Union, subject to the conclusion of the said Protocol.

The text of the Protocol is attached to this Decision.

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

3. Pending its entry into force, the Protocol shall be applied on a provisional basis by the Union and its Member States, to the extent permitted under domestic law, from the date of signing.

4. A decision to discontinue the provisional application of the Protocol and to give notice thereof to the United States of America in accordance with Article 9(2) of the Protocol, and a decision to withdraw such notice, shall be taken by the Council, on behalf of the Union and of the Member States, acting unanimously in accordance with the relevant Treaty provisions.

Article 2

Suspension of reciprocal recognition

A decision to suspend the reciprocal recognition of regulatory determinations with regard to airline fitness and citizenship and to inform the United States of America thereof in accordance with Article 6 *bis*(2) of the Agreement as amended by the Protocol shall be taken by the Council, on behalf of the Union and of the Member States, acting unanimously in accordance with the relevant Treaty provisions.

Article 3

Joint Committee

1. The Union and the Member States shall be represented in the Joint Committee established pursuant to Article 18 of the Agreement as amended by the Protocol by representatives of the Commission and of the Member States.

2. For matters that fall within the exclusive competence of the Union and do not require the adoption of a decision having legal effect, the position to be taken by the Union and its Member States within the Joint Committee shall be adopted by the Commission and shall be notified in advance to the Council and the Member States.

3. For decisions concerning matters that fall within the competence of the Union, the position to be taken by the Union and its Member States within the Joint Committee 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 provide otherwise.

4. For decisions concerning matters that fall within the competence of the Member States, the position to be taken by the Union and its Member States within the Joint Committee shall be adopted by the Council, acting by unanimity on a proposal from the Commission or from any Member State, 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 Union and of the Member States within the Joint Committee shall be presented by the Commission, except in matters that fall within the exclusive competence of the Member States, in which case it shall be presented by the Presidency of the Council or, if the Council so decides, by the Commission.

Article 4

Decisions in accordance with Article 21(5) of the Agreement

A decision not to allow airlines of the other Party to operate additional frequencies or enter new markets under the Agreement and give notice thereof to the United States of America, or to agree to lift any such decision, taken in accordance with Article 21(5) of the Agreement as amended by the Protocol, shall be adopted by the Council, on behalf of the Union and of the Member States, acting unanimously in accordance with the relevant Treaty provisions.

Article 5

Information to the Commission

Member States shall inform the Commission immediately of any requests or notifications made or received by them pursuant to Article 15 of the Agreement as amended by the Protocol.

Done at Luxembourg, 24 June 2010.

For the Council
The President
J. BLANCO LÓPEZ

PROTOCOL

to amend the Air Transport Agreement between the United States of America and the European Community and its Member States, signed on 25 and 30 April 2007

THE UNITED STATES OF AMERICA (hereinafter: 'the United States'),

of the one part; and

THE KINGDOM OF BELGIUM,

THE REPUBLIC OF BULGARIA,

THE CZECH REPUBLIC,

THE KINGDOM OF DENMARK,

THE FEDERAL REPUBLIC OF GERMANY,

THE REPUBLIC OF ESTONIA,

IRELAND,

THE HELLENIC REPUBLIC,

THE KINGDOM OF SPAIN,

THE FRENCH REPUBLIC,

THE ITALIAN REPUBLIC,

THE REPUBLIC OF CYPRUS,

THE REPUBLIC OF LATVIA,

THE REPUBLIC OF LITHUANIA,

THE GRAND DUCHY OF LUXEMBOURG,

THE REPUBLIC OF HUNGARY,

THE REPUBLIC OF MALTA,

THE KINGDOM OF THE NETHERLANDS,

THE REPUBLIC OF AUSTRIA,

THE REPUBLIC OF POLAND,

THE PORTUGUESE REPUBLIC,

ROMANIA,

THE REPUBLIC OF SLOVENIA,

THE SLOVAK REPUBLIC,

THE REPUBLIC OF FINLAND,

THE KINGDOM OF SWEDEN,

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND,

being parties to the Treaty on European Union and to the Treaty on the Functioning of the European Union and being Member States of the European Union (hereinafter: 'the Member States'),

and the EUROPEAN UNION,

of the other part;

INTENDING to build upon the framework established by the Air Transport Agreement between the United States and the European Community and its Member States, signed on 25 and 30 April 2007 (hereinafter referred to as 'the Agreement'), with the goal of opening access to markets and maximising benefits for consumers, airlines, labour, and communities on both sides of the Atlantic,

FULFILLING the mandate in Article 21 of the Agreement to negotiate expeditiously a second stage agreement that advances this goal,

RECOGNISING that the European Union replaced and succeeded the European Community as a consequence of the entry into force on 1 December 2009 of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, and that as of that date, all the rights and obligations of, and all the references to, the European Community in the Agreement apply to the European Union,

HAVE AGREED TO AMEND THE AGREEMENT AS FOLLOWS:

Article 1

Definitions

Article 1 of the Agreement shall be amended by:

1. inserting the following new definition after paragraph 2:

'2 *bis* "Citizenship determination" means a finding that an air carrier proposing to operate services under this Agreement satisfies the requirements of Article 4 regarding its ownership, effective control, and principal place of business;'

2. inserting the following new definition after paragraph 3:

'3 *bis* "Fitness determination" means a finding that an air carrier proposing to operate services under this Agreement has satisfactory financial capability and adequate managerial expertise to operate such services and is disposed to comply with the laws, regulations, and requirements that govern the operation of such services;'.

Article 2

Reciprocal Recognition of Regulatory Determinations with Regard to Airline Fitness and Citizenship

A new Article 6 *bis* shall be inserted following Article 6 as follows:

'*Article 6* bis

Reciprocal Recognition of Regulatory Determinations with Regard to Airline Fitness and Citizenship

1. Upon receipt of an application for operating authorisation, pursuant to Article 4, from an air carrier of one Party, the aeronautical authorities of the other Party shall recognise any fitness and/or citizenship determination made by the aeronautical authorities of the first Party with respect to that air carrier as if such a determination had been made by its own aeronautical authorities and not enquire further into such matters, except as provided for at subparagraph (a) below.

(a) If, after receipt of an application for operating authorisation from an air carrier, or after the grant of such authorisation, the aeronautical authorities of the receiving Party have a specific reason for concern that, despite the determination made by the aeronautical authorities of the other Party, the conditions prescribed in Article 4 of this Agreement for the grant of appropriate authorisations or permissions have not been met, then they shall promptly advise those authorities, giving substantive reasons for their concern. In that event, either Party may seek consultations, which should include representatives of the relevant aeronautical authorities, and/or additional information relevant to this concern, and such requests shall be met as soon as practicable. If the matter remains unresolved, either Party may bring the matter to the Joint Committee.

(b) This Article shall not apply to determinations in relation to safety certificates or licences; security arrangements; or insurance coverage.

2. Each Party shall inform the other in advance where practicable, and otherwise as soon as possible afterward, through the Joint Committee of any substantial changes in the criteria it applies in making the determinations referred to in paragraph 1 above. If the receiving Party requests consultations on any such change they shall be held in the Joint Committee within 30 days of such a request, unless the Parties agree otherwise. If, following such consultations, the receiving Party considers that the revised criteria of the other Party would not be satisfactory for the reciprocal recognition of regulatory determinations, the receiving Party may inform the other Party of the suspension of paragraph 1. This suspension may be lifted by the receiving Party at any time. The Joint Committee shall be informed accordingly.'

Article 3

Environment

Article 15 of the Agreement shall be deleted in its entirety and replaced with the following:

'*Article 15*

Environment

1. The Parties recognise the importance of protecting the environment when developing and implementing international aviation policy, carefully weighing the costs and benefits of measures to protect the environment in developing such policy, and, where appropriate, jointly advancing effective global solutions. Accordingly, the Parties intend to work together to limit or reduce, in an economically reasonable manner, the impact of international aviation on the environment.

2. When a Party is considering proposed environmental measures at the regional, national, or local level, 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. At the request of a Party, the other Party shall provide a description of such evaluation and mitigating steps.

3. When environmental measures are established, the aviation environmental standards adopted by the International Civil Aviation Organization in annexes to the Convention shall be followed except where differences have been filed. The Parties shall apply any environmental measures affecting air services under this Agreement in accordance with Article 2 and Article 3(4) of this Agreement.

4. The Parties reaffirm the commitment of Member States and the United States to apply the balanced approach principle.

5. The following provisions shall apply to the imposition of new mandatory noise-based operating restrictions at airports which have more than 50 000 movements of civil subsonic jet aeroplanes per calendar year.

(a) The responsible authorities of a Party shall provide an opportunity for the views of interested parties to be considered in the decision-making process.

(b) Notice of the introduction of any new operating restriction shall be made available to the other Party at least 150 days prior to the entry into force of that operating restriction. At the request of that other Party, a written report shall be provided without delay to that other Party explaining the reasons for introducing the operating restriction, the environmental objective established for the airport, and the measures that were considered to meet that objective. That report shall include the relevant evaluation of the likely costs and benefits of the various measures considered.

(c) Operating restrictions shall be (i) non-discriminatory; (ii) not more restrictive than necessary in order to achieve the environmental objective established for a specific airport; and (iii) non-arbitrary.

6. The Parties endorse and shall encourage the exchange of information and regular dialogue among experts, in particular through existing communication channels, to enhance cooperation, consistent with applicable laws and regulations, on addressing international aviation environmental impacts and mitigation solutions, including:

(a) research and development of environmentally friendly aviation technology;

(b) improvement of scientific understanding regarding aviation emissions impacts in order to better inform policy decisions;

(c) air traffic management innovation with a view to reducing the environmental impacts of aviation;

(d) research and development of sustainable alternative fuels for aviation; and

(e) exchange of views on issues and options in international fora dealing with the environmental effects of aviation, including the coordination of positions, where appropriate.

7. If so requested by the Parties, the Joint Committee, with the assistance of experts, shall work to develop recommendations that address issues of possible overlap between and consistency among market-based measures regarding aviation emissions implemented by the Parties with a view to avoiding duplication of measures and costs and reducing to the extent possible the administrative burden on airlines. Implementation of such recommendations shall be subject to such internal approval or ratification as may be required by each Party.

8. If one Party believes that a matter involving aviation environmental protection, including proposed new measures, raises concerns for the application or implementation of this Agreement, it may request a meeting of the Joint Committee, as provided in Article 18, to consider the issue and develop appropriate responses to concerns found to be legitimate.'

Article 4

Social Dimension

A new Article 17 *bis* shall be inserted following Article 17 as follows:

'*Article 17* bis

Social Dimension

1. The Parties recognise the importance of the social dimension of the Agreement and the benefits that arise when open markets are accompanied by high labour standards. The opportunities created by the Agreement are not intended to undermine labour standards or the labour-related rights and principles contained in the Parties' respective laws.

2. The principles in paragraph 1 shall guide the Parties as they implement the Agreement, including regular consideration by the Joint Committee, pursuant to Article 18, of the social effects of the Agreement and the development of appropriate responses to concerns found to be legitimate.'

Article 5

The Joint Committee

Paragraphs 3, 4, and 5 of Article 18 of the Agreement shall be deleted in their entirety and replaced with the following:

'3. The Joint Committee shall review, as appropriate, the overall implementation of the Agreement, including any effects of aviation infrastructure constraints on the exercise of rights provided for in Article 3, the effects of security measures taken pursuant to Article 9, the effects on the conditions of competition, including in the field of Computer Reservation Systems, and any social effects of the implementation of the Agreement. The Joint Committee shall also consider, on a continuing basis, individual issues or proposals that either Party identifies as affecting, or having the potential to affect, operations under the Agreement, such as conflicting regulatory requirements.

4. The Joint Committee shall also develop cooperation by:

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

(b) considering the social effects of the Agreement as it is implemented and developing appropriate responses to concerns found to be legitimate;

(c) maintaining an inventory of issues regarding government subsidies or support raised by either Party in the Joint Committee;

(d) making decisions, on the basis of consensus, concerning any matters with respect to application of paragraph 6 of Article 11;

(e) developing, where requested by the Parties, arrangements for the reciprocal recognition of regulatory determinations;

(f) fostering cooperation between the respective authorities of the Parties in efforts to develop their respective air traffic management systems with a view toward optimising the interoperability and compatibility of those systems, reducing costs, and enhancing their safety, capacity, and environmental performance;

(g) promoting the development of proposals for joint projects and initiatives in the field of aviation safety, including with third countries;

(h) encouraging continued close cooperation among the relevant aviation security authorities of the Parties, including initiatives to develop security procedures that enhance passenger and cargo facilitation without compromising security;

(i) considering whether the Parties' respective laws, regulations, and practices in areas covered by Annex 9 to the Convention (Facilitation) may affect the exercise of rights under this Agreement;

(j) fostering expert-level exchanges on new legislative or regulatory initiatives and developments, including in the fields of security, safety, the environment, aviation infrastructure (including slots), and consumer protection;

(k) fostering consultation, where appropriate, on air transport issues dealt with in international organisations and in relations with third countries, including consideration of whether to adopt a joint approach; and

(l) taking, on the basis of consensus, the decisions to which paragraph 3 of Article 1 of Annex 4 and paragraph 3 of Article 2 of Annex 4 refer.

5. The Parties share the goal of maximising the benefits for consumers, airlines, labour, and communities on both sides of the Atlantic by extending this Agreement to include third countries. To this end, the Joint Committee shall consider, as appropriate, the conditions and procedures, including any necessary amendments to this Agreement, that would be required for additional third countries to accede to this Agreement.'

Article 6

Further Expansion of Opportunities

Article 21 shall be deleted in its entirety and replaced with the following:

'Article 21

Further Expansion of Opportunities

1. The Parties commit to the shared goal of continuing to remove market access barriers in order to maximise benefits for consumers, airlines, labour, and communities on both sides of the Atlantic, including enhancing the access of their airlines to global capital markets, so as better to reflect the realities of a global aviation industry, the strengthening of the transatlantic air transportation system, and the establishment of a framework that will encourage other countries to open up their own air services markets.

2. Pursuant to the shared goal in paragraph 1, and in fulfilling its responsibilities pursuant to Article 18 to oversee implementation of this Agreement, the Joint Committee shall review annually developments, including towards the legislative changes referred to in this Article. The Joint Committee shall develop a process of cooperation in this regard including appropriate recommendations to the Parties. The European Union and its Member States shall allow majority ownership and effective control of their airlines by the United States or its nationals, on the basis of reciprocity, upon confirmation by the Joint Committee that the laws and regulations of the United States permit majority ownership and effective control of its airlines by the Member States or their nationals.

3. Upon written confirmation by the Joint Committee, in accordance with paragraph 6 of Article 18, that the laws and regulations of each Party permit majority ownership and effective control of its airlines by the other Party or its nationals:

(a) Section 3 of Annex 1 to the Agreement shall cease to have effect;

(b) airlines of the United States shall have the right to provide scheduled passenger combination services between points in the European Union and its Member States and five countries, without serving a point in the territory of the United States. These countries shall be determined by the Joint Committee within one year from the date of signature of this Protocol. The Joint Committee may amend the list, or increase the number, of such countries; and

(c) the text of Article 2 of Annex 4 to the Agreement ("Ownership and Control of Third-Country Airlines") shall cease to have effect and the text of Annex 6 to the Agreement shall take effect in its place, with regard to third-country airlines owned and controlled by the United States or its nationals.

4. Upon written confirmation by the Joint Committee, in accordance with paragraph 6 of Article 18, that the laws and regulations of the European Union and its Member States with regard to the imposition of noise-based operating restrictions at airports having more than 50 000 annual movements of civil subsonic jet aeroplanes provide that the European Commission has the authority to review the process prior to the imposition of such measures, and, where it is not satisfied that the appropriate procedures have been followed in accordance with applicable obligations, to take in that case, prior to their imposition, appropriate legal action regarding the measures in question:

(a) airlines of the European Union shall have the right to provide scheduled passenger combination services between points in the United States and five additional countries, without serving a point in the territory of the European Union and its Member States. These countries shall be determined by the Joint Committee within one year from the date of signature of this Protocol. The Joint Committee may amend the list, or increase the number, of such countries; and

(b) the text of Article 2 of Annex 4 to the Agreement ("Ownership and Control of Third-Country Airlines") shall cease to have effect and the text of Annex 6 to the Agreement shall take effect in its place, with regard to third-country airlines owned and controlled by Member States or their nationals.

5. Following written confirmation by the Joint Committee that a Party has met the conditions of paragraphs 3 and 4 that are applicable to that Party, that Party may request high-level consultations regarding the implementation of this Article. Such consultations shall commence within 60 days of the date of delivery of the request, unless otherwise agreed by the Parties. The Parties shall make every effort to resolve the matters referred to consultation. If the Party requesting consultations is dissatisfied with the outcome of the consultations, that Party may give notice in writing through diplomatic channels of its decision that no airline of the other Party shall operate additional frequencies or enter new markets under this Agreement. Any such decision shall take effect 60 days from the date of notification. Within that period, the other Party may decide that no airline of the first Party shall operate additional frequencies or enter new markets under the Agreement. Such a decision shall take effect on the same day as the decision by the first Party. Any such decision by a Party may be lifted by agreement of the Parties, which shall be confirmed in writing by the Joint Committee.'

Article 7

US Government Procured Transportation

Annex 3 to the Agreement shall be deleted in its entirety and replaced with the following:

'*ANNEX 3*

Concerning US Government Procured Transportation

Community airlines shall have the right to transport passengers and cargo on scheduled and charter flights for which a US Government civilian department, agency, or instrumentality:

(1) obtains the transportation for itself or in carrying out an arrangement under which payment is made by the Government or payment is made from amounts provided for the use of the Government; or

(2) provides the transportation to or for a foreign country or international or other organisation without reimbursement,

and that transportation is:

(a) between any point in the United States and any point outside the United States, to the extent such transportation is authorised under subparagraph 1(c) of Article 3, except – with respect to passengers who are eligible to travel on city-pair contract fares – between points for which there is a city-pair contract fare in effect; or

(b) between any two points outside the United States.

This Annex shall not apply to transportation obtained or funded by the Secretary of Defense or the Secretary of a military department.'

Article 8

Annexes

The text of the Attachment to this Protocol shall be appended to the Agreement as Annex 6.

Article 9

Provisional Application

1. Pending its entry into force, the Parties agree to provisionally apply this Protocol, to the extent permitted under applicable domestic law, from the date of signature.

2. Either Party may at any time give notice in writing through diplomatic channels to the other Party of a decision to no longer apply this Protocol. In that event, application of this Protocol shall cease at midnight GMT at the end of the International Air Transport Association (IATA) traffic season in effect one year following the date of written notification, unless notice is withdrawn by agreement of the Parties before the end of this period. In the event that provisional application of the Agreement ceases pursuant to paragraph 2 of Article 25 of the Agreement, provisional application of this Protocol shall cease simultaneously.

Article 10

Entry into Force

This Protocol shall enter into force on the later of:

1. the date of entry into force of the Agreement; and

2. one month after the date of the last note in an exchange of diplomatic notes between the Parties confirming that all necessary procedures for entry into force of this Protocol have been completed.

For purposes of this exchange of diplomatic notes, diplomatic notes to or from the European Union and its Member States shall be delivered to or from, as the case may be, the European Union. The diplomatic note or notes from the European Union and its Member States shall contain communications from each Member State confirming that its necessary procedures for entry into force of this Protocol have been completed.

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

Съставено в Люксембург на двадесет и четвърти юни две хиляди и десета година.

Hecho en Luxemburgo, el veinticuatro de junio de dos mil diez.

V Lucemburku dne dvacátého čtvrtého června dva tisíce deset.

Udfærdiget i Luxembourg den fireogtyvende juni to tusind og ti.

Geschehen zu Luxemburg am vierundzwanzigsten Juni zweitausendzehn.

Kahe tuhande kümnenda aasta juunikuu kahekümne neljandal päeval Luxembourgis.

Έγινε στο Λουξεμβούργο, στις είκοσι τέσσερις Ιουνίου δύο χιλιάδες δέκα.

Done at Luxembourg on the twenty-fourth day of June in the year two thousand and ten.

Fait à Luxembourg, le vingt-quatre juin deux mille dix.

Fatto a Lussemburgo, addì ventiquattro giugno duemiladieci.

Luksemburgā, divi tūkstoši desmitā gada divdesmit ceturtajā jūnijā.

Priimta du tūkstančiai dešimtų metų birželio dvidešimt ketvirtą dieną Liuksemburge.

Kelt Luxembourgban, a kétezer-tizedik év június havának huszonnegyedik napján.

Magħmul fil-Lussemburgu, fl-erbgħa u għoxrin jum ta' Ġunju tas-sena elfejn u għaxra.

Gedaan te Luxemburg, de vierentwintigste juni tweeduizend tien.

Sporządzono w Luksemburgu dnia dwudziestego czwartego czerwca roku dwa tysiące dziesiątego.

Feito no Luxemburgo, em vinte e quatro de Junho de dois mil e dez.

Întocmit la Luxemburg, la douăzeci și patru iunie două mii zece.

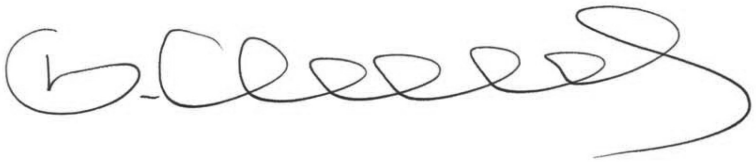
V Luxemburgu dňa dvadsiateho štvrtého júna dvetisícdesať.

V Luxembourgu, dne štiriindvajsetega junija leta dva tisoč deset.

Tehty Luxemburgissa kahdentenakymmenentenäneljäntenä päivänä kesäkuuta vuonna kaksituhattakymmenen.

Som skedde i Luxemburg den tjugofjärde juni tjugohundratio.

За Република България



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.

Diese Unterschrift bindet zugleich die Wallonische Region, die Flämische Region und die Region Brüssel-Hauptstadt.

Za Českou republiku

På Kongeriget Danmarks vegne

Für die Bundesrepublik Deutschland

Eesti Vabariigi nimel

Για την Ελληνική Δημοκρατία

Por el Reino de España

Pour la République française

Thar cheann Na hÉireann
For Ireland

Per la Repubblica italiana

Για την Κυπριακή Δημοκρατία

Latvijas Republikas vārdā

Lietuvos Respublikos vardu

Pour le Grand-Duché de Luxembourg

A Magyar Köztársaság részéről

Għal Malta

Voor het Koninkrijk der Nederlanden

Für die Republik Österreich

W imieniu Rzeczypospolitej Polskiej

Pela República Portuguesa

Pentru România

Za Republiko Slovenijo

Za Slovenskú republiku

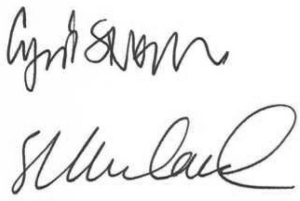
Suomen tasavallan puolesta

För Konungariket Sverige

For the United Kingdom of Great Britain and Northern Ireland

За Европейския съюз
Por la Unión Europea
Za Evropskou unii
For Den Europæiske Union
Für die Europäische Union
Euroopa Liidu nimel
Για την Ευρωπαϊκή Ένωση
For the European Union
Pour l'Union européenne
Per l'Unione europea
Eiropas Savienības vārdā
Europos Sajungos vardu
Az Európai Unió részéről
Għall-Unjoni Ewropea
Voor de Europese Unie
W imieniu Unii Europejskiej
Pela União Europeia
Pentru Uniunea Europeană
Za Európsku úniu
Za Evropsko unijo
Euroopan unionin puolesta
För Europeiska unionen

For the United States of America



Attachment to the Protocol

ANNEX 6

Ownership and Control of Third Country Airlines

1. Neither Party shall exercise any available rights under air services arrangements with a third country to refuse, revoke, suspend or limit authorisations or permissions for any airlines of that third country on the grounds that substantial ownership of that airline is vested in the other Party, its nationals, or both.

2. The United States shall not exercise any available rights under air services arrangements to refuse, revoke, suspend or limit authorisations or permissions for any airline of the Principality of Liechtenstein, the Swiss Confederation, a member of the ECAA as of the date of signature of this Agreement, or any country in Africa that is implementing an Open-Skies air services agreement with the United States as of the date of signature of this Agreement, on the grounds that effective control of that airline is vested in a Member State or States, nationals of such a state or states, or both.

3. Neither Party shall exercise available rights under air services arrangements with a third country to refuse, revoke, suspend or limit authorisations or permissions for any airlines of that third country on the grounds that effective control of that airline is vested in the other Party, its nationals, or both, provided that the third country in question has established a record of cooperation in air services relations with both Parties.

4. The Joint Committee shall maintain an inventory of third countries that are considered by both Parties to have established a record of cooperation in air services relations.

Joint Declaration

Representatives of the United States and of the European Union and its Member States confirmed that the Protocol to Amend the Air Transport Agreement between the United States of America and the European Community and its Member States, initialled in Brussels on 25 March 2010, is to be authenticated in other languages, as provided either by Exchange of Letters, before signature of the Protocol, or by decision of the Joint Committee, after signature of the Protocol.

This Joint Declaration is an integral part of the Protocol.

For the United States:	For the European Union and its Member States:
John BYERLY (signed)	Daniel CALLEJA (signed)
25 March 2010	25 March 2010

MEMORANDUM OF CONSULTATIONS

1. Delegations representing the European Union and its Member States and the United States met in Brussels 23-25 March 2010 to complete negotiations of a second stage air transport agreement. Delegation lists are appended as Attachment A.

2. The delegations reached *ad referendum* agreement on, and initialled the text of, a Protocol to Amend the Air Transport Agreement between the United States and the European Community and its Member States, signed on 25 and 30 April 2007 (the 'Protocol', appended as Attachment B). The delegations intend to submit the draft Protocol to their respective authorities for approval, with the goal of its entry into force in the near future.

3. References in this Memorandum to the Agreement and to articles, paragraphs, and annexes are to the Agreement, as it would be amended by the Protocol.

4. The EU delegation confirmed that as a consequence of the entry into force on 1 December 2009 of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, the European Union replaced and succeeded the European Community and that, as of that date, all the rights and obligations of, and all the references to, the European Community in the Agreement refer to the European Union.

5. The delegations affirmed that the procedures for reciprocal recognition of regulatory determinations with regard to airline fitness and citizenship in the new Article 6 *bis* are not intended to modify the conditions prescribed under the laws and regulations normally applied by the Parties to the operation of international air transportation referred to in Article 4 of the Agreement.

6. With respect to Article 9, the delegations expressed their desire to further EU/US cooperation on aviation security, with the aim of achieving, wherever possible, maximum reliance on each other's security measures, consistent with applicable laws and regulations, to reduce unnecessary duplication of such measures.

7. The delegations noted that security cooperation is expected to include regular consultations on amendments to existing requirements, where feasible prior to their implementation; close coordination of airport assessment activities and, where possible and appropriate, air carrier inspections; and exchange of information on new security technologies and procedures.

8. With a view to fostering efficient use of the resources available, enhancing security, and promoting facilitation, the delegations noted the benefit of swift and, wherever possible, coordinated responses to new threats.

9. Both delegations noted that the provisions of the respective conventions in force between a Member State and the United States for the avoidance of double taxation on income and on capital remain unaffected by the Protocol.

10. With respect to paragraph 7 of Article 15, the EU delegation noted that the issues to be addressed by any work in this area would be expected to include, among other things, the environmental effectiveness and technical integrity of the respective measures, the need to avoid competitive distortion and carbon leakage and, where appropriate, whether and how such measures may be linked or integrated with each other. The US delegation noted that in developing recommendations, it would expect to focus, inter alia, on consistency with the Chicago Convention and the promotion of the objectives of the Agreement.

11. The two delegations emphasised that nothing in the Agreement affects in any way their respective legal and policy positions on various aviation-related environmental issues.

12. In recognition of shared environmental objectives, the delegations developed a Joint Statement on Environmental Cooperation appended as Attachment C to this Memorandum of Consultations.

13. The EU delegation restated the EU's intention to continue to work through the United Nations Framework Convention on Climate Change to establish global emissions reduction targets for international aviation.

14. The US and EU delegations restated the US and EU intentions to work through the International Civil Aviation Organization (ICAO) to address greenhouse gas emissions from international aviation. Both delegations also noted the contributions from industry in support of this process.

15. Both delegations noted that the references to the balanced approach in paragraph 4 of Article 15 refer to Resolution A35-5 unanimously adopted at the 35th ICAO Assembly. The delegations emphasised that all aspects of the balanced approach principle established in that Resolution are relevant and important, including the recognition that 'States have relevant legal obligations, existing agreements, current laws and established policies which may influence their implementation of the ICAO balanced approach'.

16. Both delegations underscored their support for applying ICAO's 'Guidance on the Balanced Approach to Aircraft Noise', which is currently published in ICAO Document 9829 (2nd edition).

17. With regard to paragraph 5(a) of Article 15, the EU delegation noted that 'interested parties' is defined in Article 2(f) of Directive 2002/30/EC to mean 'natural or legal persons affected or likely to be affected by, or having a legitimate interest in the introduction of, noise reduction measures, including operating restrictions'. The EU delegation also noted that, pursuant to Article 10 of that Directive, Member States must ensure that, for the application of Articles 5 and 6 of that Directive, procedures for consultation of interested parties are established in accordance with applicable national law.

18. Recognising the challenges related to the increasing cross-border mobility of workers and structure of companies, the EU delegation noted that the European Commission is closely monitoring the situation and is considering further initiatives in order to improve implementation, application, and enforcement in this area. The EU delegation also referred to the work being undertaken by the European Commission on transnational company agreements and stated its willingness to inform the Joint Committee about these and other related initiatives, as appropriate.

19. The US delegation noted that, in the United States, the principle that allows for selection of a single representative for a defined class or craft of employees at an airline has helped promote rights for both airline flight and ground workers to organise themselves and to negotiate and enforce collective bargaining agreements.

20. Both delegations noted that, in the event that a Party would take measures contrary to the Agreement, including Article 21, the other Party may avail itself of any appropriate and proportional measures in accordance with international law, including the Agreement.

21. In relation to paragraph 4 of Article 21, the EU delegation noted that the review referred to in that paragraph will be exercised by the European Commission *ex officio* or *ex parte*.

22. The delegations noted that the traffic rights referred to in paragraph 4(a) of Article 21 would be in addition to those granted to the European Union and its Member States in Article 3 of the Agreement.

23. The delegations expressed their satisfaction with the cooperation between the US Department of Transportation and the European Commission, as provided for in the Agreement, with the shared objective of improving each other's understanding of the laws, procedures and practices of each other's competition regimes and the impact that developments in the air transportation industry have had, or are likely to have, on competition in the sector.

24. The delegations affirmed the commitment of the respective competition authorities to dialogue and cooperation and to the principle of transparency, consistent with legal requirements, including the protection of confidential commercial information. The delegations further affirmed the willingness of the respective competition authorities to provide guidance on procedural requirements, where appropriate.

25. The delegations noted that any communication to the Joint Committee or elsewhere relating to the cooperation under Annex 2 must respect the rules governing disclosure of confidential or market-sensitive information.

26. For the purposes of paragraph 4 of Annex 6, the delegations expressed their expectation that the Joint Committee will develop, within one year of signature of the Protocol, appropriate criteria for determining whether countries have established a record of cooperation in air services relations.

27. The delegations welcomed the participation of representatives of Iceland and Norway as observers on the EU delegation and noted that work will continue in the Joint Committee to develop a proposal regarding conditions and procedures for Iceland and Norway to accede to the Agreement, as amended by the Protocol.

28. Both delegations expressed their expectation that their respective aeronautical authorities would permit operations consistent with the terms of the Agreement, as amended by the Protocol, on the basis of comity and reciprocity, or on an administrative basis, from the date of signature of the Protocol.

For the Delegation of the European Union and its Member States

Daniel CALLEJA

For the Delegation of the United States of America

John BYERLY

Attachment C

Joint Statement on Environmental Cooperation

The delegations of the United States and the European Union and its Member States reaffirmed the critical importance of addressing the environmental impacts of international aviation. They expressed their shared commitment to the environmental objectives established at the 35th Assembly of the International Civil Aviation Organization (ICAO), namely to strive to:

(a) limit or reduce the number of people affected by significant aircraft noise;

(b) limit or reduce the impact of aviation emissions on local air quality; and

(c) limit or reduce the impact of aviation greenhouse gas emissions on the global climate.

The delegations acknowledged the outcome of the 15th Conference of the Parties of the United Nations Framework Convention on Climate Change and the Copenhagen Accord, including the shared recognition of the scientific view that the increase in global temperature should be below two degrees Celsius.

The delegations confirmed the Parties' strong desire and willingness to work together to build upon the progress achieved by the ICAO High Level Meeting on International Aviation and Climate Change by seeking to join with international partners in a collective effort at ICAO to establish a more ambitious program of action, including robust goals, a framework for market-based measures, and considerations for the special needs of developing countries.

Both sides noted their commitment to cooperate within the ICAO Committee on Aviation Environmental Protection (CAEP) to ensure the timely and effective delivery of its work programme, including adoption of a global aircraft CO_2 standard and other measures on climate change, noise, and air quality.

The delegations emphasised the importance of reducing the environmental impacts of aviation through:

— continuing cooperation on the NextGen and SESAR air traffic management modernisation programmes, including the Atlantic Interoperability Initiative to Reduce Emissions (AIRE),

— fostering and accelerating, as appropriate, the development and implementation of new aircraft technologies and sustainable alternative fuels, including through the Clean Sky Joint Technology Initiative, the Continuous Low Energy, Emissions and Noise (CLEEN) Program, the Commercial Aviation Alternative Fuels Initiative (CAAFI), and the Sustainable Way for Alternative Fuel and Energy in Aviation (SWAFEA) initiative, and

— collaborating with the scientific community through, for example, the CAEP Impacts and Science Group to better understand and quantify the effects of aviation on the environment, such as health and non-CO_2 climate impacts.

REGULATIONS

COMMISSION REGULATION (EU) No 756/2010

of 24 August 2010

amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes IV and V

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC [1], and in particular Article 7(4)(a), Article 7(5) and Article 14 thereof,

Whereas:

(1) Regulation (EC) No 850/2004 implements in the law of the Union the commitments set out in the Stockholm Convention on Persistent Organic Pollutants (hereinafter 'the Convention') approved by Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants [2] and in the Protocol to the 1979 Convention on Long-range Transboundary Air Pollution on Persistent Organic Pollutants (hereinafter 'the Protocol') approved by Council Decision 2004/259/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long-range Transboundary Air Pollution on Persistent Organic Pollutants [3].

(2) Following nominations of substances received from the European Union and its Member States, Norway and Mexico, the Persistent Organic Pollutants Review Committee established under the Convention has concluded its work on the nine proposed substances, which have been found to meet the criteria of the Convention. At the fourth meeting of the Conference of the Parties to the Convention from 4 to 8 May 2009 (hereinafter 'COP4') it was agreed to add all nine substances to the Annexes to the Convention.

(3) Annexes IV and V to Regulation (EC) No 850/2004 should be amended in order to take into account the new substances that have been listed during the COP4.

(4) The COP4 decided to list chlordecone, hexabromobiphenyl and hexachlorocyclohexanes, including lindane, in Annex A (elimination) to the Convention. Those substances are included in Annexes IV and V to Regulation (EC) No 850/2004 since they were listed by the Protocol.

(5) The COP4 decided to list pentachlorobenzene in Annex A (elimination) to the Convention. Therefore, pentachlorobenzene should be listed in Annexes IV and V to Regulation (EC) No 850/2004, indicating the corresponding maximum concentration limits, which have been set applying the methodology used for establishing the limit values for persistent organic pollutants (hereinafter 'POPs') in Council Regulation (EC) No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants [4] and in Council Regulation (EC) No 172/2007 of 16 February 2007 amending Annex V to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants [5]. Those provisional maximum concentration limits should be reviewed in view of the results of a study on the implementation of the waste-related provisions of Regulation (EC) No 850/2004, to be conducted on behalf of the Commission.

(6) The COP4 decided to list Perfluorooctane sulfonic acid and its derivatives (hereinafter 'PFOS') in Annex B (restriction) to the Convention, with some exemptions for specific applications. The use of PFOS is currently allowed for some specific applications. Because of the lifespan of articles containing PFOS, these

[1] OJ L 158, 30.4.2004, p. 7.
[2] OJ L 209, 31.7.2006, p. 1.
[3] OJ L 81, 19.3.2004, p. 35.
[4] OJ L 217, 8.8.2006, p. 1.
[5] OJ L 55, 23.2.2007, p. 1.

articles will continue to enter the waste stream for some years, although in decreasing volumes. There may be practical difficulties of identifying certain materials containing PFOS within a given waste stream. Data on quantities and concentrations of PFOS in articles and wastes is currently still not sufficient. Extending the obligation in Regulation (EC) No 850/2004 to destroy or irreversibly transform the POP content to PFOS for waste exceeding the concentration limits of Annex IV could have impacts on existing recycling schemes, which may challenge another environmental priority of ensuring the sustainable use of resources. In view of this, PFOS is listed in Annexes IV and V without an indication of the concentration limits.

(7) The COP4 decided to list tetrabromodiphenyl ether, pentabromodiphenyl ether, hexabromodiphenyl ether and heptabromodiphenyl ether, hereinafter 'polybrominated diphenyl ethers', in Annex A (elimination) to the Convention. Placing on the market and use of pentabromodiphenyl ether and octabromodiphenyl ether have been restricted in the Union by virtue of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency [1], with a maximum concentration limit of 0,1 % by weight. Pentabromodiphenyl ether, hexabromodiphenyl ether, heptabromodiphenyl ether and tetrabromodiphenyl ether are not currently being placed on the market in the Union as they are restricted by Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII [2] and Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment [3]. However, because of the lifespan of products containing those polybrominated diphenyl ethers, end-of-life products containing these substances will continue to enter the waste stream for some years. Taking into account the practical difficulties of identifying materials containing polybrominated diphenyl ethers within a mixed waste fraction and the current lack of comprehensive scientific data on quantities and concentrations of polybrominated diphenyl ethers in articles and wastes, extending the obligation to destroy or irreversibly transform the POP content to these new substances for waste exceeding the concentration limits of Annex IV could endanger existing recycling schemes and thus hinder the sustainable use of resources. This problem was acknowledged by the COP4 and special exemptions were agreed for continued recycling of wastes that contain listed polybrominated diphenyl ethers even if this may lead to recycling of the POPs. Therefore, those exceptions should be reflected in Regulation (EC) No 850/2004.

(8) Uniform maximum concentration limits are required in the Union in order to avoid a distortion of the internal market. Provisional maximum concentration limits have been set for pentachlorobenzene in Annexes IV and V to Regulation (EC) No 850/2004 based on available data and under application of the precautionary principle.

(9) In view of the lack of comprehensive scientific information on quantities and concentrations in articles and wastes, as well as exposure scenarios, at this stage, no maximum concentration limits can be established for PFOS and polybrominated diphenyl ethers in Annexes IV and V to Regulation (EC) No 850/2004. Subject to further information becoming available and a review by the Commission, maximum concentration limits for the nine POPs will be proposed, taking into account the objectives of the POP Regulation.

(10) In accordance with Article 22 of the Convention, the amendments to Annexes A, B and C thereto enter into force one year from the date of communication by the depositary of an amendment, which will fall on 26 August 2010. Consequently and for reasons of coherence, this Regulation should apply from the same date.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Council Directive 75/442/EEC [4]. This Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

1. Annex IV to Regulation (EC) No 850/2004 is replaced by Annex I to this Regulation.

2. Annex V to Regulation (EC) No 850/2004 is amended in accordance with Annex II to this Regulation.

[1] OJ L 396, 30.12.2006, p. 1.
[2] OJ L 164, 26.6.2009, p. 7.
[3] OJ L 37, 13.2.2003, p. 19.
[4] OJ L 194, 25.7.1975, p. 39.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 26 August 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 August 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

'ANNEX IV

List of substances subject to waste management provisions set out in Article 7

Substance	CAS No	EC No	Concentration limit referred to in Article 7(4)(a)
Tetrabromodiphenyl ether $C_{12}H_6Br_4O$			
Pentabromodiphenyl ether $C_{12}H_5Br_5O$			
Hexabromodiphenyl ether $C_{12}H_4Br_6O$			
Heptabromodiphenyl ether $C_{12}H_3Br_7O$			
Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, Metal salt (O-M^+), halide, amide, and other derivatives including polymers)			
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)			15 µg/kg (1)
DDT (1,1,1-trichloro-2,2-bis (4-chlorophenyl)ethane)	50-29-3	200-024-3	50 mg/kg
Chlordane	57-74-9	200-349-0	50 mg/kg
Hexachlorocyclohexanes, including lindane	58-89-9 319-84-6 319-85-7 608-73-1	210-168-9 200-401-2 206-270-8 206-271-3	50 mg/kg
Dieldrin	60-57-1	200-484-5	50 mg/kg
Endrin	72-20-8	200-775-7	50 mg/kg
Heptachlor	76-44-8	200-962-3	50 mg/kg
Hexachlorobenzene	118-74-1	200-273-9	50 mg/kg
Chlordecone	143-50-0	205-601-3	50 mg/kg
Aldrin	309-00-2	206-215-8	50 mg/kg
Pentachlorobenzene	608-93-5	210-172-5	50 mg/kg
Polychlorinated Biphenyls (PCB)	1336-36-3 and others	215-648-1	50 mg/kg (2)
Mirex	2385-85-5	219-196-6	50 mg/kg
Toxaphene	8001-35-2	232-283-3	50 mg/kg

Substance	CAS No	EC No	Concentration limit referred to in Article 7(4)(a)
Hexabromobiphenyl	36355-01-8	252-994-2	50 mg/kg

([1]) The limit is calculated as PCDD and PCDF according to the following toxic equivalency factors (TEFs):

PCDD	TEF
2,3,7,8-TeCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0,1
1,2,3,6,7,8-HxCDD	0,1
1,2,3,7,8,9-HxCDD	0,1
1,2,3,4,6,7,8-HpCDD	0,01
OCDD	0,0003
PCDF	TEF
2,3,7,8-TeCDF	0,1
1,2,3,7,8-PeCDF	0,03
2,3,4,7,8-PeCDF	0,3
1,2,3,4,7,8-HxCDF	0,1
PCDD	TEF
1,2,3,6,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDF	0,1
2,3,4,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDF	0,01
1,2,3,4,7,8,9-HpCDF	0,01
OCDF	0,0003

([2]) Where applicable, the calculation method laid down in European standards EN 12766-1 and EN 12766-2 shall be applied.'

ANNEX II

In Annex V, Part 2, to Regulation (EC) No 850/2004 the table is replaced by the following:

'Wastes as classified in Commission Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV (1)	Operation
10	WASTES FROM THERMAL PROCESSES	Aldrin: 5 000 mg/kg; Chlordane: 5 000 mg/kg; Chlordecone: 5 000 mg/kg; DDT (1,1,1-trichloro-2,2-bis (4-chloro-phenyl) ethane): 5 000 mg/kg; Dieldrin: 5 000 mg/kg; Endrin: 5 000 mg/kg; Heptabromodiphenyl ether ($C_{12}H_3Br_7O$); Heptachlor: 5 000 mg/kg; Hexabromobiphenyl: 5 000 mg/kg; Hexabromodiphenyl ether ($C_{12}H_4Br_6O$); Hexachlorobenzene: 5 000 mg/kg; Hexachlorocyclohexanes, including lindane: 5 000 mg/kg; Mirex: 5 000 mg/kg; Pentabromodiphenyl ether ($C_{12}H_5Br_5O$); Pentachlorobenzene: 5 000 mg/kg; Perfluorooctane sulfonic acid and its derivatives (PFOS) ($C_8F_{17}SO_2X$) (X = OH, Metal salt (O-M^+), halide, amide, and other derivatives including polymers); Polychlorinated Biphenyls (PCB) (5): 50 mg/kg; Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF) (6): 5 mg/kg; Tetrabromodiphenyl ether ($C_{12}H_6Br_4O$); Toxaphene: 5 000 mg/kg;	Permanent storage shall be allowed only when all the following conditions are met: 1. the storage takes place in one of the following locations: — safe, deep, underground, hard rock formations, — salt mines, — a landfill site for hazardous waste, provided that the waste is solidified or partly stabilised where technically feasible as required for classification of the waste in Subchapter 1903 of Decision 2000/532/EC; 2. the provisions of Council Directive 1999/31/EC (3) and Council Decision 2003/33/EC (4) were respected; 3. it has been demonstrated that the selected operation is environmentally preferable.
10 01	Wastes from power stations and other combustion plants (except 19)		
10 01 14 * (2)	Bottom ash, slag and boiler dust from co-incineration containing dangerous substances		
10 01 16 *	Fly ash from co-incineration containing dangerous substances		
10 02	Wastes from the iron and steel industry		
10 02 07 *	Solid wastes from gas treatment containing dangerous substances		
10 03	Wastes from aluminium thermal metallurgy		
10 03 04 *	Primary production slag		
10 03 08 *	Salt slag from secondary production		
10 03 09 *	Black dross from secondary production		
10 03 19 *	Flue-gas dust containing dangerous substances		
10 03 21 *	Other particulates and dust (including ball mill dust) containing dangerous substances		
10 03 29 *	Wastes from treatment of salt slag and black dross containing dangerous substances		
10 04	Wastes from lead thermal metallurgy		
10 04 01 *	Slag from primary and secondary production		

Wastes as classified in Commission Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV [1]	Operation
10 04 02 *	Dross and skimming from primary and secondary production		
10 04 04 *	Flue-gas dust		
10 04 05 *	Other particulates and dust		
10 04 06 *	Solid wastes from gas treatment		
10 05	Wastes from zinc thermal metallurgy		
10 05 03 *	Flue-gas dust		
10 05 05 *	Solid waste from gas treatment		
10 06	Wastes from copper thermal metallurgy		
10 06 03 *	Flue-gas dust		
10 06 06 *	Solid wastes from gas treatment		
10 08	Wastes from other non-ferrous thermal metallurgy		
10 08 08 *	Salt slag from primary and secondary production		
10 08 15 *	Flue-gas dust containing dangerous substances		
10 09	Wastes from casting of ferrous pieces		
10 09 09 *	Flue-gas dust containing dangerous substances		
16	WASTES NOT OTHERWISE SPECIFIED IN THE LIST		
16 11	Waste linings and refractories		
16 11 01 *	Carbon-based linings and refractories from metallurgical processes containing dangerous substances		
16 11 03 *	Other linings and refractories from metallurgical processes containing dangerous substances		

Wastes as classified in Commission Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV [1]	Operation
17	CONSTRUCTION AND DEMOLITION WASTES (INCLUDING EXCAVATED SOIL FROM CONTAMINATED SITES)		
17 01	Concrete, bricks, tiles and ceramics		
17 01 06 *	Mixtures of, or separate fractions of concrete, bricks, tiles and ceramics containing dangerous substances		
17 05	Soil including excavated soil from contaminated sites, stones and dredging spoil		
17 05 03 *	Inorganic fraction of soil and stones containing dangerous substances		
17 09	Other construction and demolition wastes		
17 09 02 *	Construction and demolition wastes containing PCB, excluding PCB containing equipment		
17 09 03 *	Other construction and demolition wastes containing dangerous substances		
19	WASTES FROM WASTE MANAGEMENT FACILITIES, OFF-SITE WASTE WATER TREATMENT PLANTS AND THE PREPARATION OF WATER INTENDED FOR HUMAN CONSUMPTION AND WATER FROM INDUSTRIAL USE		
19 01	Wastes from incineration or pyrolysis of waste		
19 01 07 *	Solid wastes from gas treatment		
19 01 11 *	Bottom ash and slag containing dangerous substances		
19 01 13 *	Fly ash containing dangerous substances		
19 01 15 *	Boiler dust containing dangerous substances		

Wastes as classified in Commission Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV (1)	Operation
19 04	Vitrified waste and waste from vitrification		
19 04 02 *	Fly ash and other flue-gas treatment wastes		
19 04 03 *	Non-vitrified solid phase		

(1) These limits apply exclusively to a landfill site for hazardous waste and do not apply to permanent underground storage facilities for hazardous wastes, including salt mines.
(2) Any waste marked with an asterisk * is considered as hazardous waste pursuant to Directive 91/689/EEC and subject to the provisions of that Directive.
(3) OJ L 182, 16.7.1999, p. 1.
(4) OJ L 11, 16.1.2003, p. 27.
(5) The calculation method laid down in European standards EN 12766-1 and EN 12766-2 shall apply.
(6) The limit is calculated as PCDD and PCDF according to the following toxic equivalency factors (TEFs):

PCDD	TEF
2,3,7,8-TeCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0,1
1,2,3,6,7,8-HxCDD	0,1
1,2,3,7,8,9-HxCDD	0,1
1,2,3,4,6,7,8-HpCDD	0,01
OCDD	0,0003
PCDF	TEF
2,3,7,8-TeCDF	0,1
1,2,3,7,8-PeCDF	0,03
2,3,4,7,8-PeCDF	0,3
1,2,3,4,7,8-HxCDF	0,1
1,2,3,6,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDF	0,1
PCDD	TEF
2,3,4,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDF	0,01
1,2,3,4,7,8,9-HpCDF	0,01
OCDF	0,0003’

COMMISSION REGULATION (EU) No 757/2010

of 24 August 2010

amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC [1], and in particular Article 14(1) thereof,

Whereas:

(1) Regulation (EC) No 850/2004 implements in the law of the Union the commitments set out in the Stockholm Convention on Persistent Organic Pollutants (hereinafter 'the Convention') approved by Council Decision 2006/507/EC of 14 October 2004 concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants [2] and in the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (hereinafter 'the Protocol') approved by Council Decision 2004/259/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants [3].

(2) Following nominations of substances received from the European Union and its Member States, Norway and Mexico, the Persistent Organic Pollutants Review Committee established under the Convention has concluded its work on the nine proposed substances, which have been found to meet the criteria of the Convention. At the fourth meeting of the Conference of the Parties to the Convention on 4–8 May 2009 (hereinafter 'COP4') it was agreed to add all nine substances to the Annexes to the Convention.

(3) In view of the decisions taken at COP4 it is necessary to update Annexes I and III to Regulation (EC) No 850/2004. Annex I to Regulation (EC) No 850/2004 should be amended to take into account that substances can be listed only in the Convention.

(4) The COP4 decided to list eight of the substances in Annex A (elimination) to the Convention. The ninth substance, Perfluorooctane sulfonic acid and its derivatives (hereinafter PFOS) is still widely used worldwide and COP4 decided to list it in Annex B (restriction) with a range of exemptions. Regulation (EC) No 850/2004 has a similar structure with Annex I (prohibition) and Annex II (restriction). The Convention contains obligations to prohibit or restrict production, use, import and export of the substances listed in its Annexes A and B. By listing the substance covered by the COP4 decisions in Regulation (EC) No 850/2004, the scope of the restriction is brought in conformity with the COP4 decision as Regulation (EC) No 850/2004 includes conditions for production, use and waste management in addition to restricting placing on the market.

(5) Placing on the market and use of PFOS has been restricted in the Union by virtue of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [4]. The existing restriction on PFOS in the Union contains only few exemptions compared to those included in the COP4 decision. PFOS was also listed in Annex I to the revised Protocol adopted on 18 December 2009. Therefore PFOS should be listed together with the other eight substances in Annex I to Regulation (EC) No 850/2004. Derogations that were applicable for PFOS when listed in Annex XVII are carried over and listed in Annex I to Regulation (EC) No 850/2004 with only few amendments. The derogations should be subject to the use of best available technique where applicable. The specific derogation to use PFOS as wetting agents for use in controlled electroplating systems is time limited in accordance with the COP4 decision. If technically justified the deadline can be prolonged, subject to approval by the Conference of the Parties to the Convention. Member States must report every four years on the use of the allowed derogations. The European Union as a Party to the Convention should report to it based on the Member State reports. The Commission should continue to review the remaining derogations and the availability of safer alternative substances or technologies.

(6) The provisions in Article 4(1)(b) of Regulation (EC) No 850/2004 regarding substances occurring as an unintentional trace contaminant should be defined for PFOS to ensure a harmonised enforcement and control of that Regulation, while at the same time guaranteeing conformity with the Convention. By virtue of Annex XVII to Regulation (EC) No 1907/2006 PFOS was

[1] OJ L 158, 30.4.2004, p. 7.
[2] OJ L 209, 31.7.2006, p. 1.
[3] OJ L 81, 19.3.2004, p. 35.
[4] OJ L 396, 30.12.2006, p. 1.

allowed to be used in quantities below certain thresholds. Until further information becomes available, the thresholds in Annex XVII to Regulation (EC) No 1907/2006 for PFOS in articles correspond to a level below which PFOS can not be meaningfully used while enabling control and enforcement through existing methods. These thresholds should therefore limit the use of PFOS to a level corresponding to unintentional trace contaminants. For PFOS as substances or in preparations, this Regulation should establish a threshold corresponding to a similar level. To rule out intentional use, this level should be lower than the level applied in Regulation (EC) No 1907/2006.

(7) Placing on the market and use of pentabromodiphenyl ether and octabromodiphenyl ether have been restricted in the Union by virtue of Annex XVII to Regulation (EC) No 1907/2006 with a maximum concentration limit of 0,1 % by weight below which it is not considered restricted. The COP4 decided to list congeners present in the commercial forms of pentabromodiphenyl ethers and octabromodiphenyl ethers having POPs characteristics. For reasons of coherence the listing in Regulation (EC) No 850/2004 should follow the approach of Annex XVII to Regulation (EC) No 1907/2006 for those derivatives identified by COP4 as having POP characteristics; therefore hexabromodiphenyl ether, heptabromodiphenyl ether, tetrabromodiphenyl ether and pentabromodiphenyl ether derivatives should be listed in Annex I to Regulation (EC) No 850/2004.

(8) The provisions in Article 4(1)(b) of Regulation (EC) No 850/2004 regarding substances occurring as an unintentional trace contaminant should be defined for polybrominated diphenyl ethers (PBDEs) to ensure a harmonised enforcement and control of that Regulation, while at the same time guaranteeing conformity with the Convention. This Regulation should establish a fixed threshold for considering unintentional trace contaminants regarding PBDEs in substances, preparations and articles. Subject to further information that becomes available and a review by the Commission, in line with the objectives of this Regulation, the thresholds in Annex XVII to Regulation (EC) No 1907/2006 for PBDEs in articles produced from recycled materials should limit the use of PBDEs to unintentional trace contaminants in that they are considered to correspond to a level below which PBDEs can not be meaningfully used while enabling control and enforcement through existing methods. For PBDEs as substances, in preparations or in articles, this Regulation should establish a threshold corresponding to a similar level.

(9) It is necessary to clarify that the prohibition in Article 3 of Regulation (EC) No 850/2004 does not apply to articles containing PBDEs and PFOS already in use on the date of entry into force of this Regulation.

(10) DDT and Hexachlorocyclohexanes (HCH), including lindane, should be listed without derogations. Part A of Annex I to Regulation (EC) No 850/2004 allows Member States to maintain existing production and use of DDT for the production of dicofol. No Member State is currently using the derogation. In addition, dicofol was denied for inclusion in Annex I to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1] as well as in Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [2]. That derogation should therefore be deleted. HCH, including lindane, is listed in Part B of Annex I Regulation (EC) No 850/2004, with two specific derogations for certain specific uses. The derogations expired on 1 September 2006 and on 31 December 2007 and should therefore be deleted.

(11) In conformity with the COP4 decisions pentachlorobenzene should be added to Annexes I and III to Regulation (EC) No 850/2004 so that it becomes subject to a general prohibition as well as the release reduction provisions in that Regulation. Chlordecone and hexabromobiphenyl should be moved to Annex I, Part A as they are now listed to both international instruments.

(12) In accordance with Article 22 of the Convention, amendments to Annexes A, B and C thereto enter into force one year from the date of communication by the depositary of an amendment, which will fall on 26 August 2010. Consequently and for reasons of coherence this Regulation should apply from the same date. This Regulation should therefore enter into force as a matter of urgency.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Directive 67/548/EEC,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and III to Regulation (EC) No 850/2004 are amended in accordance with the Annex to this Regulation.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 230, 19.8.1991, p. 1.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 26 August 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 August 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

(1) Annex I to Regulation (EC) No 850/2004 is replaced by the following:

'ANNEX I

Part A — Substances listed in the Convention and in the Protocol as well as substances listed only in the Convention

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
Tetrabromodiphenyl ether $C_{12}H_6Br_4O$			1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of Tetrabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles. 2. By way of derogation, the production, placing on the market and use of the following shall be allowed: (a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of tetrabromodiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use; (b) electrical and electronic equipment within the scope of Directive 2002/95/EC of the European Parliament and Council (*). 3. Use of articles already in use in the Union before 25 August 2010 containing Tetrabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Pentabromodiphenyl ether $C_{12}H_5Br_5O$			1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of pentabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles. 2. By way of derogation, the production, placing on the market and use of the following shall be allowed: (a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of pentabromodiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use;

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			(b) electrical and electronic equipment within the scope of Directive 2002/95/EC. 3. Use of articles already in use in the Union before 25 August 2010 containing Pentabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Hexabromodiphenyl ether $C_{12}H_4Br_6O$			1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of hexabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles. 2. By way of derogation, the production, placing on the market and use of the following shall be allowed: (a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of hexabromobiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use; (b) electrical and electronic equipment within the scope of Directive 2002/95/EC. 3. Use of articles already in use in the Union before 25 August 2010 containing Hexabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Heptabromodiphenyl ether $C_{12}H_3Br_7O$			1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of heptabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances, preparations, articles or as constituents of the flame-retarded parts of articles. 2. By way of derogation, the production, placing on the market and use of the following shall be allowed: (a) without prejudice to subparagraph (b), articles and preparations containing concentrations below 0,1 % of heptabromodiphenyl ether by weight when produced partially or fully from recycled materials or materials from waste prepared for re-use;

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			(b) electrical and electronic equipment within the scope of Directive 2002/95/EC. 3. Use of articles already in use in the Union before 25 August 2010 containing Heptabromodiphenyl ether as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, Metal salt (O-M^+), halide, amide, and other derivatives including polymers)			1. For the purposes of this entry, Article 4(1)(b) shall apply to concentrations of PFOS equal to or below 10 mg/kg (0,001 % by weight) when it occurs in substances or in preparations. 2. For the purposes of this entry, Article 4(1) (b) shall apply to concentrations of PFOS in semi-finished products or articles, or parts thereof, if the concentration of PFOS is lower than 0,1 % by weight calculated with reference to the mass of structurally or micro-structurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is lower than 1 μg/m^2 of the coated material. 3. Use of articles already in use in the Union before 25 August 2010 containing PFOS as a constituent of such articles shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles. 4. Fire-fighting foams that were placed on the market before 27 December 2006 may be used until 27 June 2011. 5. If the quantity released into the environment is minimised, production and placing on the market is allowed for the following specific uses provided that Member States report to the Commission every four years on progress made to eliminate PFOS: (a) until 26 August 2015, wetting agents for use in controlled electroplating systems; (b) photoresists or anti reflective coatings for photolithography processes; (c) photographic coatings applied to films, papers, or printing plates;

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			(d) mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems; (e) hydraulic fluids for aviation. Where derogations in points (a) to (e) above concern the production or use in an installation within the scope of Directive 2008/1/EC of the European Parliament and of the Council (**), the relevant best available techniques for the prevention and minimisation of emissions of PFOS described in the information published by the Commission pursuant to Article 17(2), second subparagraph, of Directive 2008/1/EC shall apply. As soon as new information on details of uses and safer alternative substances or technologies for the uses in points (b) to (e) becomes available, the Commission shall review the derogations in the second subparagraph so that: (i) the uses of PFOS will be phased out as soon as the use of safer alternatives is technically and economically feasible, (ii) a derogation can only be continued for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on, (iii) releases of PFOS into the environment have been minimised by applying best available techniques. 6. Once standards are adopted by the European Committee for Standardisation (CEN) they shall be used as the analytical test methods for demonstrating the conformity of substances, preparations and articles to paragraphs 1 and 2.
DDT (1,1,1-trichloro-2,2-bis(4-chlorophenyl)ethane)	50-29-3	200-024-3	—
Chlordane	57-74-9	200-349-0	—
Hexachlorocyclohexanes, including lindane	58-89-9 319-84-6 319-85-7 608-73-1	200-401-2 206-270-8 206-271-3 210-168-9	—

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
Dieldrin	60-57-1	200-484-5	—
Endrin	72-20-8	200-775-7	—
Heptachlor	76-44-8	200-962-3	—
Hexachlorobenzene	118-74-1	200-273-9	—
Chlordecone	143-50-0	205-601-3	—
Aldrin	309-00-2	206-215-8	—
Pentachlorobenzene	608-93-5	210-172-5	—
Polychlorinated Biphenyls (PCB)	1336-36-3 and others	215-648-1 and others	Without prejudice to Directive 96/59/EC, articles already in use at the time of the entry into force of this Regulation are allowed to be used
Mirex	2385-85-5	219-196-6	—
Toxaphene	8001-35-2	232-283-3	—
Hexabromobiphenyl	36355-01-8	252-994-2	—

(*) OJ L 37, 13.2.2003, p. 19.
(**) OJ L 24, 29.1.2008, p. 8.

Part B — Substances listed only in the Protocol

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
—’			

(2) In Annex III the following substance is added:

‘Pentachlorobenzene (CAS No 608-93-5)’

COMMISSION REGULATION (EU) No 758/2010

of 24 August 2010

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance valnemulin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council [1], and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) The maximum residue limit for pharmacologically active substances intended for use in the European Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin [2].

(3) Valnemulin is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance for porcine, applicable to muscle, liver and kidney.

(4) An application for the extension of the existing entry for valnemulin to include rabbits has been submitted to the European Medicines Agency.

(5) The Committee for Medicinal Products for Veterinary Use has recommended the extension of that entry to cover rabbits, applicable to muscle, liver and kidney.

(6) The entry for valnemulin in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include rabbits.

(7) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from 24 October 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 August 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 152, 16.6.2009, p. 11.
[2] OJ L 15, 20.1.2010, p. 1.

ANNEX

The entry Valnemulin in Table 1 of the Annex to Regulation (EU) No 37/2010 shall be replaced by the following:

Pharmacologically active Substance	Marker residue	Animal species	MRL	Target tissues	Other provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
'Valnemulin	Valnemulin	Porcine, rabbit	50 µg/kg	Muscle	NO ENTRY	Anti-infectious agents/Antibiotics'
			500 µg/kg	Liver		
			100 µg/kg	Kidney		

COMMISSION REGULATION (EU) No 759/2010

of 24 August 2010

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance tildipirosin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council [1], and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) The maximum residue limit for pharmacologically active substances intended for use in the European Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.

(2) Pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin [2].

(3) An application for the establishment of maximum residue limits (hereinafter 'MRL') for tildipirosin in bovine and porcine species has been submitted to the European Medicines Agency.

(4) The Committee for Medicinal Products for Veterinary Use (hereinafter 'CVMP') recommended establishing a provisional MRL for tildipirosin for bovine species, applicable to muscle, fat, liver and kidney, excluding animals producing milk for human consumption. The provisional MRL set out for muscle should not apply to the injection site, where residue levels should not exceed 11 500 μg/kg.

(5) According to Article 5 of Regulation (EC) No 470/2009 the European Medicines Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for another species. The CVMP recommended to extrapolate the provisional MRLs for tildipirosin from bovine to caprine species.

(6) The CVMP recommended establishing provisional MRLs for tildipirosin for porcine species, applicable to muscle, skin, fat, liver and kidney. The provisional MRL set out for muscle should not apply to the injection site, where residue levels should not exceed 7 500 μg/kg.

(7) Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended to include the substance tildipirosin for bovine, caprine and porcine species. The provisional MRLs set out in that table for tildipirosin for bovine, caprine and porcine species should expire on 1 January 2012.

(8) It is appropriate to provide for a reasonable period of time for the stakeholders concerned to take measures that may be required to comply with the newly set MRL.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

[1] OJ L 152, 16.6.2009, p. 11.
[2] OJ L 15, 20.1.2010, p. 1.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from 24 October 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 August 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the following substance is inserted in alphabetical order:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
'Tildipirosin	Tildipirosin	Bovine, caprine	400 µg/kg 200 µg/kg 2 000 µg/kg 3 000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption. The MRL for muscle shall not apply to the injection site, where residue levels shall not exceed 11 500 µg/kg. Provisional MRL shall expire on 1 January 2012.	Macrolide'
		Porcine	1 200 µg/kg 800 µg/kg 5 000 µg/kg 10 000 µg/kg	Muscle Skin and fat Liver Kidney	The MRL for muscle shall not apply to the injection site, where residue levels shall not exceed 7 500 µg/kg. Provisional MRL shall expire on 1 January 2012.	

COMMISSION REGULATION (EU) No 760/2010

of 24 August 2010

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2], and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 25 August 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 August 2010.

For the Commission,
On behalf of the President,
Jean-Luc DEMARTY
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	TR	103,0
	ZZ	103,0
0707 00 05	TR	132,5
	ZZ	132,5
0709 90 70	TR	122,5
	ZZ	122,5
0805 50 10	AR	113,6
	CL	123,2
	TR	151,3
	UY	118,5
	ZA	139,7
	ZZ	129,3
0806 10 10	BA	91,2
	EG	281,8
	TR	120,1
	ZZ	164,4
0808 10 80	AR	114,0
	BR	66,8
	CL	91,6
	CN	65,6
	NZ	90,0
	US	119,5
	UY	95,9
	ZA	94,6
	ZZ	92,3
0808 20 50	AR	115,4
	CL	150,5
	CN	80,6
	TR	133,1
	ZA	94,5
	ZZ	114,8
0809 30	TR	135,8
	ZZ	135,8
0809 40 05	BA	59,9
	IL	160,9
	XS	59,4
	ZA	191,2
	ZZ	117,9

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

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