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Price: EUR 4

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⁽¹⁾ Text with EEA relevance

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 22 October 2013

concerning the conclusion of the Agreement between the European Union and the Republic of Armenia on the facilitation of the issuance of visas

(2013/628/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular point (a) of Article 77(2), in conjunction with point (a) of the second subparagraph of Article 218(6), thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

- (1) In accordance with Council Decision 2013/2/EU ⁽¹⁾, the Agreement between the European Union and the Republic of Armenia on the facilitation of the issuance of visas ('the Agreement') was signed on 17 December 2012, subject to its conclusion at a later date.
- (2) The Agreement should be approved.
- (3) This Decision constitutes a development of the provisions of the Schengen *acquis* in which the United Kingdom does not take part, in accordance with Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* ⁽²⁾; the United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.
- (4) This Decision constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the

Schengen *acquis* ⁽³⁾; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application.

- (5) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

The Agreement between the European Union and the Republic of Armenia on the facilitation of the issuance of visas is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Union, give the notification provided for in Article 14(1) of the Agreement ⁽⁴⁾.

Article 3

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

Done at Luxembourg, 22 October 2013.

For the Council

The President

L. LINKEVIČIUS

⁽¹⁾ OJ L 3, 8.1.2013, p. 1.

⁽²⁾ OJ L 131, 1.6.2000, p. 43.

⁽³⁾ OJ L 64, 7.3.2002, p. 20.

⁽⁴⁾ The date of entry into force of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

AGREEMENT**between the European Union and the Republic of Armenia on the facilitation of the issuance of visas**

THE EUROPEAN UNION, hereinafter referred to as 'the Union',

and

THE REPUBLIC OF ARMENIA, hereinafter referred to as 'Armenia',

hereinafter referred to as 'the Parties',

DESIRING to facilitate people-to-people contacts as an important condition for a steady development of economic, humanitarian, cultural, scientific and other ties by facilitating the issuing of visas to citizens of Armenia,

BEARING IN MIND the Partnership and Cooperation Agreement between the Union and its Member States, of the one part, and Armenia, of the other part, as well as the intention of the Parties to conclude an EU-Armenia Association Agreement,

HAVING REGARD to the Joint Declarations of the Prague and Warsaw Eastern Partnership Summits held respectively on 7 May 2009 and on 30 September 2011 stating the political support towards visa liberalization of the visa regime in a secure environment,

REAFFIRMING the intention to take gradual steps towards a visa-free travel regime for their citizens in due course, provided that conditions for well-managed and secure mobility are in place,

BEARING IN MIND that, as from 10 January 2013, all citizens of the Union are exempted from the visa requirement when travelling to Armenia for a period of time not exceeding 90 days or transiting through the territory of Armenia,

RECOGNISING that if Armenia reintroduces visa requirements for the citizens of the Union or certain categories of them, the same facilitations granted under this Agreement to the citizens of Armenia would automatically, on the basis of reciprocity, apply to the citizens of the Union concerned,

BEARING IN MIND that these visa requirements can only be reintroduced for all citizens of the Union or certain categories of citizens of the Union,

RECOGNISING that visa facilitation should not lead to illegal immigration and paying special attention to security and readmission,

TAKING INTO ACCOUNT the Protocol on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice and the Protocol of the Schengen *acquis* integrated into the framework of the European Union, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, and confirming that the provisions of this Agreement do not apply to the United Kingdom and Ireland,

TAKING INTO ACCOUNT the Protocol on the position of Denmark annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union and confirming that the provisions of this agreement do not apply to the Kingdom of Denmark,

HAVE AGREED AS FOLLOWS:

*Article 1***Purpose and scope of application**

1. The purpose of this Agreement is to facilitate the issuance of visas for an intended stay of no more than 90 days per period of 180 days to the citizens of Armenia.

2. If Armenia reintroduces the visa requirements for the citizens of the Union or certain categories of them, the same facilitations granted under this Agreement to the citizens of Armenia would automatically, on the basis of reciprocity, apply to the citizens of the Union concerned,

*Article 2***General clause**

1. The visa facilitations provided in this Agreement shall apply to citizens of Armenia only insofar as they are not exempted from the visa requirement by the laws and regulations of the Union or the Member States, this Agreement or other international agreements.

2. The national law of Armenia or of the Member States or the Union law shall apply to issues not covered by the provisions of this Agreement, such as the refusal to issue a visa, recognition of travel documents, proof of sufficient means of subsistence and the refusal of entry and expulsion measures.

Article 3

Definitions

For the purpose of this Agreement:

- (a) 'Member State' shall mean any Member State of the European Union, with the exception of the Kingdom of Denmark, the Republic of Ireland and the United Kingdom of Great Britain and Northern Ireland;
- (b) 'citizen of the Union' shall mean a national of a Member State as defined in point (a);
- (c) 'citizen of Armenia' shall mean any person who holds the citizenship of Armenia in accordance with the legislation of the Republic of Armenia;
- (d) 'visa' shall mean an authorisation issued by a Member State with a view to transiting through or an intended stay of a duration of no more than 90 days in any 180-day period in the territory of Member States;
- (e) 'legally residing person' shall mean a citizen of Armenia authorized or entitled to stay for more than 90 days in the territory of a Member State, on the basis of Union law or national legislation.

Article 4

Documentary evidence regarding the purpose of the journey

1. For the following categories of citizens of Armenia, the following documents are sufficient for justifying the purpose of the journey to the other Party:

- (a) for close relatives – spouses, children (including adopted), parents (including custodians), grandparents, grandchildren visiting citizens of Armenia legally residing in the Member States, or citizens of the Union residing in the territory of the Member State of which they are nationals:
 - a written request from the host person;
- (b) for members of official delegations including permanent members of such delegations who, following an official invitation addressed to Armenia, shall participate in meetings, consultations, negotiations or exchange programmes, as well as in events held in the territory of one of the Member States by intergovernmental organisations:
 - a letter issued by a competent authority of Armenia confirming that the applicant is a member of its delegation, respectively a permanent member of its delegation, travelling to the territory of the other Party to participate in the aforementioned events, accompanied by a copy of the official invitation;
- (c) for pupils, students, post-graduate persons and accompanying teachers who undertake trips for the purposes of study or educational training, including in the framework of exchange programmes as well as other school-related activities:

- a written request or a certificate of enrolment from the host university, college or school or student cards or certificates of the courses to be attended;
- (d) for persons travelling for medical reasons and necessary accompanying persons:
 - an official document of the medical institution confirming necessity of medical care in this institution, the necessity of being accompanied and proof of sufficient financial means to pay for the medical treatment;
- (e) for journalists and technical crew accompanying them in a professional capacity:
 - a certificate or other document issued by a professional organisation or the applicant's employer proving that the person concerned is a qualified journalist and stating that the purpose of the journey is to carry out journalistic work or proving that he/she is a member of the technical crew accompanying the journalist in a professional capacity;
- (f) for participants in international sport events and persons accompanying them in a professional capacity:
 - a written request from the host organisation, competent authorities, national sport federations or national Olympic committees of the Member State;
- (g) for business people and representatives of business organisations:
 - a written request from the host legal person or company, organisation or an office or a branch of such legal person or company, state or local authorities of the Member States or organising committees or trade and industrial exhibitions, conferences and symposia held in the territories of one of the Member States, endorsed by the competent authorities in accordance with the national legislation;
- (h) for members of the professions participating in international exhibitions, conferences, symposia, seminars or other similar events:
 - a written request from the host organisation confirming that the person concerned is participating in the event;
- (i) for representatives of civil society organisations and persons invited by Armenian community non-profit organisations registered in the Member States when undertaking trips for the purposes of educational training, seminars, conferences, including in the framework of exchange programmes or Pan-Armenian and community support programmes:
 - a written request issued by the host organisation, a confirmation that the person is representing the civil society organisation or participating in Pan-Armenian or community support activities and the certificate on establishment of such organisation from the relevant register issued by a state authority in accordance with the national legislation;

(j) for persons participating in scientific, academic, cultural or artistic activities, including university and other exchange programmes:

— a written request from the host organisation to participate in the activities;

(k) for drivers conducting international cargo and passenger transportation services to the territories of the Member States in vehicles registered in Armenia:

— a written request from the national association (union) of carriers of Armenia providing for international road transportation, stating the purpose, itinerary, duration and frequency of the trips;

(l) for participants of the official exchange programmes organised by twin cities and other municipal entities:

— a written request of the Head of Administration/Mayor of these cities or municipal authorities;

(m) for visiting military and civil burial grounds:

— an official document confirming the existence and preservation of the grave as well as family or other relationship between the applicant and the buried.

2. For the purposes of this Article the written request shall include the following items:

(a) for the invited person: name and surname, date of birth, sex, citizenship, passport number, time and purpose of the journey, number of entries and where relevant the name of the spouse and children accompanying the invited person;

(b) for the inviting person: name, surname and address;

(c) for the inviting legal person, company or organisation: full name and address and:

— if the request is issued by an organisation or authority, the name and position of the person who signs the request,

— if the inviting person is a legal person or company or an office or a branch of such legal person or company established in the territory of a Member State, the registration number as required by the national law of the Member State concerned.

3. For the categories of persons mentioned in paragraph 1 of this Article, all categories of visas are issued according to the simplified procedure without requiring any other justification, invitation or validation concerning the purpose of the journey, provided for by the legislation of the Parties.

Article 5

Issuance of multiple-entry visas

1. Diplomatic missions and consular posts of the Member States shall issue multiple-entry visas with a term of validity of 5 years to the following categories of persons:

(a) spouses, children (including adopted), who are under the age of 21 or are dependent and parents (including custodians), visiting citizens of Armenia legally residing in the Member States, or citizens of the Union residing in the territory of the Member State of which they are nationals;

(b) members of national and regional governments and of constitutional and supreme courts if they are not exempted from the visa requirement by this Agreement, in the exercise of their duties;

(c) permanent members of official delegations who, following an official invitation addressed to Armenia, are to participate regularly in meetings, consultations, negotiations or exchange programmes, as well as in events held in the territory of the Member States by intergovernmental organisations;

By way of derogation, where the need or the intention to travel frequently or regularly is manifestly limited to a shorter period, the term of validity of the multiple-entry visa shall be limited to that period, in particular where:

— in the case of the persons referred to in point (a), the period of validity of the authorisation for legal residence of citizens of Armenia legally residing in the Union,

— in case of the persons referred to in point (b), the term of office,

— in the case of the persons referred to in point (c), the term of the validity of the status as a permanent member of an official delegation,

is less than five years.

2. Diplomatic missions and consular posts of the Member States shall issue multiple-entry visas with the term of validity of one year to the following categories of persons, provided that during the previous year they have obtained at least one visa and have made use of it in accordance with the laws on entry and stay of the visited State:

(a) members of official delegations who, following an official invitation addressed to Armenia, shall participate regularly in meetings, consultations, negotiations or exchange programmes, as well as in events held in the territory of the Member States by intergovernmental organisations;

- (b) representatives of civil society organisations and persons invited by Armenian community non-profit organisations registered in the Member States when undertaking trips to the Member States for the purposes of educational training, seminars, conferences, including in the framework of exchange programmes or Pan-Armenian and community support programmes;
- (c) members of the professions participating in international exhibitions, conferences, symposia, seminars or other similar events who regularly travel to the Member States;
- (d) persons participating in scientific, cultural or artistic activities, including university and other exchange programmes, who regularly travel to the Member States;
- (e) students and post-graduate persons who regularly travel for the purposes of study or educational training, including in the framework of exchange programmes;
- (f) participants of the official exchange programmes organised by twin cities and other municipal entities;
- (g) persons needing to visit regularly for medical reasons and necessary accompanying persons;
- (h) journalists and technical crew accompanying them in a professional capacity;
- (i) business people and representatives of business organisations who regularly travel to the Member States;
- (j) participants in international sports events and persons accompanying them in a professional capacity;
- (k) drivers conducting international cargo and passenger transportation services to the territories of the Member States in vehicles registered in Armenia.

By way of derogation from the first sentence, where the need or the intention to travel frequently or regularly is manifestly limited to a shorter period, the term of validity of the multiple-entry visa shall be limited to that period.

3. Diplomatic missions and consular posts of the Member States shall issue multiple-entry visas with the term of validity of a minimum of 2 years and a maximum of 5 years to the categories of persons referred to in paragraph 2 of this Article, provided that during the previous 2 years they have made use of the one year multiple-entry visas in accordance with the laws on entry and stay of the visited State unless the need or the intention to travel frequently or regularly is manifestly limited to a shorter period, in which case the term of validity of the multiple-entry visa shall be limited to that period.

4. The total period of stay of persons referred to in paragraphs 1 to 3 of this Article shall not exceed 90 days per period of 180 days in the territory of the Member States.

Article 6

Fees for processing visa applications

1. The fee for processing visa applications shall amount to EUR 35.

The aforementioned amount may be reviewed in accordance with the procedure provided for in Article 14(4).

2. Without prejudice to paragraph 3 of this Article, fees for processing the visa application are waived for the following categories of persons:

- (a) pensioners;
- (b) children under the age of 12;
- (c) members of national and regional governments and of Constitutional and Supreme courts, in case they are not exempted from the visa requirement by this Agreement;
- (d) persons with disabilities and the persons accompanying them, if necessary;
- (e) close relatives – spouse, children (including adopted), parents (including custodians), grandparents or grandchildren – of citizens of Armenia legally residing in the territory of the Member States, or citizens of the Union residing in the territory of the Member State of which they are nationals;
- (f) members of official delegations, including permanent members of official delegations, who, following an official invitation addressed to Armenia, shall participate in meetings, consultations, negotiations or exchange programmes, as well as in events held in the territory of one of the Member States by intergovernmental organisations;
- (g) pupils, students, post-graduate students and accompanying teachers who undertake trips for the purposes of study or educational training, including exchange programmes as well as other school-related activities;
- (h) journalists and technical crew accompanying them in a professional capacity;
- (i) participants in international sport events and persons accompanying them in a professional capacity;
- (j) representatives of civil society organisations and persons invited by Armenian community non-profit organisations registered in the Member States when undertaking trips for the purposes of educational training, seminars, conferences, including in the framework of exchange programmes or Pan-Armenian and community support programmes;
- (k) persons participating in scientific, academic, cultural or artistic activities, including university and other exchange programmes;
- (l) persons who have presented documents proving the necessity of their travel on humanitarian grounds, including to receive urgent medical treatment and the person accompanying such person, or to attend a funeral of a close relative or to visit a seriously ill close relative.

3. If a Member State cooperates with an external service provider in view of issuing a visa the external service provider may charge a service fee. This fee shall be proportionate to the costs incurred by the external service provider while performing its tasks and shall not exceed EUR 30. The Member States shall maintain the possibility for all applicants to lodge their applications directly at their consulates.

For the Union, the external service provider shall conduct its operations in accordance with the Visa Code and in full respect of Armenian legislation.

Article 7

Length of procedures for processing visa applications

1. Diplomatic missions and consular posts of the Member States shall take a decision on the request to issue a visa within 10 calendar days of the date of the receipt of the application and documents required for issuing the visa.

2. The period of time for taking a decision on a visa application may be extended up to 30 calendar days in individual cases, notably when further scrutiny of the application is needed.

3. The period of time for taking a decision on a visa application may be reduced to 2 working days or less in urgent cases.

4. If applicants are required to obtain an appointment for the lodging of an application, the appointment shall, as a rule, take place within a period of two weeks from the date when the appointment was requested. In justified cases of urgency, the consulate may allow applicants to lodge their applications either without appointment, or an appointment shall be given immediately.

Article 8

Departure in case of lost or stolen documents

Citizens of the Union and of Armenia who have lost their identity documents, or from whom these documents have been stolen while staying in the territory of Armenia or the Member States, may leave the territory of Armenia or the Member States on the basis of valid identity documents entitling them to cross the border issued by diplomatic missions or consular posts of the Member States or of Armenia without any visa or other authorisation.

Article 9

Extension of visa in exceptional circumstances

Citizens of Armenia who are not able to leave the territory of the Member States by the time stated in their visas for reasons of force majeure or humanitarian reasons shall have the term of their visas extended free of charge in accordance with the legislation applied by the receiving Member State for the period required for their return to the State of their residence.

Article 10

Diplomatic passports

1. Citizens of Armenia who are holders of valid diplomatic passports may enter, leave and transit through the territories of the Member States without visas.

2. Persons referred in paragraph 1 of this Article may stay without visas in the territories of Member States for a period not exceeding 90 days per period of 180 days.

Article 11

Territorial validity of visas

Subject to the national rules and regulations concerning national security of the Member States and subject to Union rules on visas with limited territorial validity, citizens of Armenian shall be entitled to travel within the territory of the Member States on equal basis with citizens of the Union.

Article 12

Joint Committee for management of the Agreement

1. The Parties shall set up a Joint Committee of experts (hereinafter referred to as 'the Committee'), composed by representatives of the Union and of Armenia. The Union shall be represented by the Commission, assisted by experts from the Member States.

2. The Committee shall, in particular, have the following tasks:

- (a) monitoring the implementation of this Agreement;
- (b) suggesting amendments or additions to this Agreement;
- (c) settling disputes arising out of the interpretation or application of the provisions in this Agreement.

3. The Committee shall meet whenever necessary at the request of one of the Parties and at least once a year.

4. The Committee shall establish its rules of procedure.

Article 13

Relation of this Agreement with bilateral Agreements between Member States and Armenia

As from its entry into force, this Agreement shall take precedence over provisions of any bilateral or multilateral agreements or arrangements concluded between individual Member States and Armenia, in so far as the provisions of the latter agreements or arrangements cover issues dealt with by this Agreement.

Article 14

Final clauses

1. This Agreement shall be ratified or approved by the Parties in accordance with their respective procedures and shall enter into force on the first day of the second month following the date on which the Parties notify each other that the procedures referred to above have been completed.

2. By way of derogation from paragraph 1 of this Article, this Agreement shall only enter into force on the date of the entry into force of the Agreement between the European Union and Armenia on readmission if this date is after the date provided for in paragraph 1 of this Article.

3. This Agreement is concluded for an indefinite period of time, unless terminated in accordance with paragraph 6 of this Article.

4. This Agreement may be amended by written agreement of the Parties. Amendments shall enter into force after the Parties have notified each other of the completion of their internal procedures necessary for this purpose.

5. Each Party may suspend in whole or in part this Agreement for reasons of public order, protection of national security or protection of public health. The decision on

suspension shall be notified to the other Party not later than 48 hours before its entry into force. The Party that has suspended the application of this Agreement shall immediately inform the other Party once the reasons for the suspension no longer apply.

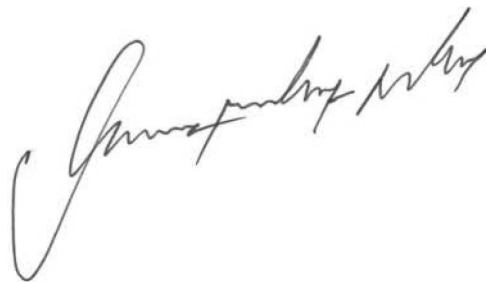
6. Each Party may terminate this Agreement by giving written notice to the other Party. This Agreement shall cease to be in force 90 days after the date of such notification.

Done at Brussels on 17 December 2012, in duplicate, in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Armenian languages, each of these texts being equally authentic.

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 Sąjungos 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
Եվրոպական Միության կողմից



За Република Армения
Por la República de Armenia
Za Arménskou republiku
For Republikken Armenien
Für die Republik Armenien
Armenia Vabariigi nimel
Για τη Δημοκρατία της Αρμενίας
For the Republic of Armenia
Pour la République d'Arménie
Per la Repubblica di Armenia
Armēnijas Republikas vārdā –
Armēnijos Respublikos vardu
Örmény Köztársaság részéről
Għar-Repubblika tal-Armenja
Voor de Republiek Armenië
W imieniu Republiki Armenii
Pela República da Arménia
Pentru Republica Armenia
Za Arménsku republiku
Za Republiko Armenijo
Armenian tasavallan puolesta
För Republiken Armenien
Հայաստանի Հանրապետության կողմից



PROTOCOL**to the Agreement on the Member States that do not fully apply the Schengen *acquis***

Those Member States which are bound by the Schengen *acquis* but which do not issue yet Schengen visas, while awaiting the relevant decision of the Council to that end, shall issue national visas the validity of which is limited to their own territory.

In accordance with Decision No 582/2008/EC of the European Parliament and of the Council of 17 June 2008 introducing a simplified regime for the control of persons at the external borders based on the unilateral recognition by Bulgaria, Cyprus and Romania of certain documents as equivalent to their national visas for the purposes of transit through their territories ⁽¹⁾, harmonised measures have been taken in order to simplify the transit of holders of Schengen visa and Schengen residence permits through the territory of the Member States that do not fully apply the Schengen *acquis* yet.

⁽¹⁾ OJ L 161, 20.6.2008, p. 30.

Joint Declaration on Article 10 of the agreement on diplomatic passports

The Union or Armenia might invoke a partial suspension of the agreement and in particular of Article 10, in accordance with the procedure set up by Article 14(5), if the implementation of Article 10 is abused by the other Party or leads to a threat to public security.

In case of suspension of the implementation of Article 10, both Parties shall initiate consultations within the framework of the Joint Committee set up by the Agreement with a view to solve the problems that lead to the suspension.

As a priority, both Parties declare their commitment to ensure a high level of document security for diplomatic passports, in particular by integrating biometric identifiers. For the Union, this will be ensured in compliance with the requirements set out in Council Regulation (EC) No 2252/2004 of 13 December 2004 on standards for security features and biometrics in passports and travel documents issued by Member States ⁽¹⁾.

European Union Declaration on documents to be submitted when applying for short stay visas

The European Union will intensify efforts and endeavour to draw up, before the entry into force of the Agreement between the European Union and the Republic of Armenia on the facilitation of the issuance of visas, a list of minimum requirements in order to ensure that Armenian applicants are given coherent and uniform basic information, in accordance with point (a) of Article 47(1) of the Visa Code, and are required to submit, in principle, the same supporting documents.

The information mentioned above is to be disseminated widely (on the information board of consulates, in leaflets, on websites, etc.).

⁽¹⁾ OJ L 385, 29.12.2004, p. 1.

Joint Declaration concerning Denmark

The Parties take note that the present Agreement does not apply to the procedures for issuing visas by the diplomatic missions and consular services of Denmark.

In such circumstances, it is appropriate that the authorities of Denmark and of Armenia conclude, without delay, a bilateral agreement on the facilitation of the issuance of short-stay visas in similar terms as the Agreement between the Union and Armenia.

Joint declaration concerning the United Kingdom and Ireland

The Parties take note that the present Agreement does not apply to the territory of the United Kingdom and Ireland.

In such circumstances, it is appropriate that the authorities of the United Kingdom, Ireland and Armenia conclude bilateral agreements on the facilitation of the issuance of visas.

Joint declaration concerning Iceland, Norway, Switzerland and Liechtenstein

The Parties take note of the close relationship between the Union and Switzerland, Iceland, Liechtenstein, and Norway, particularly by virtue of the Agreements of 18 May 1999 and 26 October 2004 concerning the association of these countries with the implementation, application and development of the Schengen *acquis*.

In such circumstances, it is appropriate that the authorities of Switzerland, Iceland, Liechtenstein, and Norway and Armenia conclude, without delay, bilateral agreements on the facilitation of the issuance of short-stay visas in similar terms as the Agreement between the Union and Armenia.

Joint declaration on cooperation on travel documents

The Parties agree that the Joint Committee established under Article 12 of the Agreement, when monitoring the implementation of the Agreement, should evaluate the impact of the level of security of the respective travel documents on the functioning of the Agreement. To that end, the Parties agree to regularly inform each other about the measures taken for avoiding the proliferation of travel documents, developing the technical aspects of travel document security as well as regarding the personalisation process of the issuance of travel documents.

COUNCIL DECISION**of 22 October 2013****on the conclusion of the Agreement between the European Union and the Republic of Armenia on the readmission of persons residing without authorisation**

(2013/629/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 79(3), in conjunction with point (a) of the second subparagraph of Article 218(6), thereof

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

- (1) In accordance with Council Decision 2013/156/EU ⁽¹⁾, the Agreement between the European Union and the Republic of Armenia on readmission of persons residing without authorisation ('the Agreement') was signed on 19 April 2013, subject to its conclusion at a later date.
- (2) The Agreement should be approved.
- (3) The Agreement establishes a Joint Readmission Committee which may adopt its rules of procedure. It is appropriate to provide for a simplified procedure for the establishment of the Union position in this case.
- (4) In accordance with Articles 1 and 2 of Protocol No 21 on the position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, those Member States are not taking part in the adoption of this Decision and are not bound by it or subject to its application.
- (5) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on

European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

The Agreement between the European Union and the Republic of Armenia on readmission of persons residing without authorisation is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Union, give the notification provided for in Article 23(2) of the Agreement ⁽²⁾.

Article 3

The Commission, assisted by experts from Member States, shall represent the Union in the Joint Readmission Committee established by Article 19 of the Agreement.

Article 4

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

Done at Luxembourg, 22 October 2013.

For the Council

The President

L. LINKEVIČIUS

⁽¹⁾ OJ L 87, 27.3.2013, p. 1.

⁽²⁾ The date of entry into force of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

AGREEMENT**between the European Union and the Republic of Armenia on the readmission of persons residing without authorisation**

THE CONTRACTING PARTIES,

THE EUROPEAN UNION, hereinafter referred to as 'the Union',

and

THE REPUBLIC OF ARMENIA, hereinafter referred to as 'Armenia',

DETERMINED to strengthen their cooperation in order to combat illegal immigration more effectively,

DESIRING to establish, by means of this Agreement and on the basis of reciprocity, rapid and effective procedures for the identification and safe and orderly return of persons who do not, or no longer, fulfil the conditions for entry to, presence in, or residence, on the territory of Armenia or one of the Member States of the European Union, and to facilitate the transit of such persons in a spirit of cooperation,

EMPHASISING that this Agreement shall be without prejudice to the rights, obligations and responsibilities of the Union, its Member States and Armenia arising from international law and, in particular, from the Convention of 28 July 1951 relating to the Status of Refugees as amended by the Protocol of 31 January 1967, and the Convention of 4 November 1950 for the Protection of Human Rights and Fundamental Freedoms,

CONSIDERING that in accordance with Protocol No 21 on the position of the United Kingdom of Great Britain and Northern Ireland and of Ireland in respect of the area of Freedom, Security and Justice annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, the United Kingdom of Great Britain and Northern Ireland and Ireland will not take part in this Agreement unless they notify their wish to that effect in accordance with that Protocol,

CONSIDERING that the provisions of this Agreement, which falls within the scope of Title V of Part Three of the Treaty on the Functioning of the European Union, do not apply to the Kingdom of Denmark, in accordance with the Protocol No 22 on the position of the Kingdom of Denmark annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union,

HAVE AGREED AS FOLLOWS:

*Article 1***Definitions**

For the purpose of this Agreement:

- (a) 'Contracting Parties' shall mean Armenia and the Union;
- (b) 'National of Armenia' shall mean any person who holds the citizenship of Armenia in accordance with the legislation of the Republic of Armenia;
- (c) 'National of a Member State' shall mean any person who holds the nationality, as defined for Union purposes, of a Member State;
- (d) 'Member State' shall mean any Member State of the European Union bound by this Agreement;
- (e) 'Third-country national' shall mean any person who holds a nationality other than that of Armenia or one of the Member States;
- (f) 'Stateless person' shall mean any person who does not hold a nationality;
- (g) 'Residence permit' shall mean a permit of any type issued by Armenia or one of the Member States entitling a person to reside on its territory. This shall not include temporary permissions to remain on its territory in connection with the processing of an asylum application or an application for a residence permit;
- (h) 'Visa' shall mean an authorisation issued or a decision taken by Armenia or one of the Member States which is required with a view to entry in, or transit through, its territory. This shall not include airport transit visa;
- (i) 'Requesting State' shall mean the State (Armenia or one of the Member States) submitting a readmission application pursuant to Article 8 or a transit application pursuant to Article 15 of this Agreement;
- (j) 'Requested State' shall mean the State (Armenia or one of the Member States) to which a readmission application pursuant to Article 8 or a transit application pursuant to Article 15 of this Agreement is addressed;
- (k) 'Competent authority' shall mean any national authority of Armenia or one of the Member States entrusted with the implementation of this Agreement in accordance with Article 20(1)(a) thereof;
- (l) 'Transit' shall mean the passage of a third country national or a stateless person through the territory of the Requested State while travelling from the Requesting State to the country of destination;
- (m) 'Border region' shall mean an area which extends up to 15 kilometres from the territories of seaports including custom zones, and international airports of the Member States and Armenia.

Article 2

Fundamental principles

While strengthening cooperation on preventing and combating irregular migration, the Requested and Requesting State shall, in the application of this Agreement to persons falling within its scope, ensure respect for human rights and for the obligations and responsibilities following from relevant international instruments applicable to them, in particular:

- the Universal Declaration of the Human Rights of 10 December 1948,
- the Convention of 4 November 1950 for the Protection of Human Rights and Fundamental Freedoms,
- the International Covenant of 16 December 1966 on Civil and Political Rights,
- the UN Convention of 10 December 1984 against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment,
- the Convention of 28 July 1951 relating to the Status of Refugees and the Protocol of 31 January 1967 relating to the Status of Refugees.

The Requested State shall in particular ensure, in compliance with its obligations under the international instruments listed above, the protection of the rights of persons readmitted to its territory.

The Requesting State should give preference to voluntary return over forced return where there are no reasons to believe that this would undermine the return of a person to the Requested State.

SECTION I

READMISSION OBLIGATIONS BY ARMENIA

Article 3

Readmission of own nationals

1. Armenia shall readmit, upon application by a Member State and without further formalities other than those provided for in this Agreement, all persons who do not, or who no longer, fulfil the conditions in force for entry to, presence in, or residence on, the territory of the Requesting Member State provided that it is proved, or may be validly assumed on the basis of *prima facie* evidence furnished, that they are nationals of Armenia.

2. Armenia shall also readmit:

- minor unmarried children of the persons mentioned in paragraph 1, regardless of their place of birth or their nationality, unless they have an independent right of

residence in the Requesting Member State or hold a valid residence permit issued by another Member State,

- spouses, holding another nationality or being stateless, of the persons mentioned in paragraph 1, provided they have the right to enter and stay or receive the right to enter and stay in the territory of Armenia, unless they have an independent right of residence in the Requesting Member State or hold a valid residence permit issued by another Member State.

3. Armenia shall also readmit persons who have renounced the nationality of Armenia since entering the territory of a Member State, unless such persons have at least been promised naturalisation by that Member State.

4. After Armenia has given a positive reply to the readmission application, the competent diplomatic or consular representation of Armenia shall, irrespective of the will of the person to be readmitted, immediately, free of charge and not later than within three working days, issue the travel document required for the return of the person to be readmitted with a period of validity of 120 days. If Armenia has not, within three working days, issued the travel document, it shall be deemed to accept the use of the EU standard travel document for expulsion purposes ⁽¹⁾.

5. If, for legal or factual reasons, the person concerned cannot be transferred within the period of validity of the travel document that was initially issued, the competent diplomatic or consular representation of Armenia shall, within three working days and free of charge, issue a new travel document with a period of validity of the same duration. If Armenia has not, within three working days, issued the new travel document, it shall be deemed to accept the use of the EU standard travel document for expulsion purposes ⁽²⁾.

Article 4

Readmission of third-country nationals and stateless persons

1. Armenia shall readmit, upon application by a Member State and without further formalities other than those provided for in this Agreement, all third-country nationals or stateless persons who do not, or who no longer, fulfil the conditions in force for entry to, presence in, or residence on, the territory of the Requesting Member State provided that it is proved, or may be validly assumed on the basis of *prima facie* evidence furnished, that such persons:

- (a) hold at the time of submission of the readmission application a valid visa or residence permit issued by Armenia; or
- (b) illegally and directly entered the territory of the Member States after having stayed on, or transited through, the territory of Armenia.

⁽¹⁾ In line with the form set out in EU Council recommendation of 30 November 1994.

⁽²⁾ Ibid.

2. The readmission obligation in paragraph 1 shall not apply if the third country national or stateless person has only been in airside transit via an international airport of Armenia.

3. Without prejudice to Article 7(2), after Armenia has given a positive reply to the readmission application, the Requesting Member State issues to the person whose readmission has been accepted the EU standard travel document for expulsion purposes⁽³⁾.

SECTION II

READMISSION OBLIGATIONS BY THE UNION

Article 5

Readmission of own nationals

1. A Member State shall readmit, upon application by Armenia and without further formalities other than those provided for in this Agreement, all persons who do not, or who no longer, fulfil the conditions in force for entry to, presence in, or residence on, the territory of Armenia provided that it is proved, or may be validly assumed on the basis of prima facie evidence furnished, that they are nationals of that Member State.

2. A Member State shall also readmit:

- minor unmarried children of the persons mentioned in paragraph 1, regardless of their place of birth or their nationality, unless they have an independent right of residence in Armenia,
- spouses, holding another nationality or being stateless, of the persons mentioned in paragraph 1, provided they have the right to enter and stay or receive the right to enter and stay in the territory of the Requested Member State, unless they have an independent right of residence in Armenia.

3. A Member State shall also readmit persons who have renounced the nationality of a Member State since entering the territory of Armenia, unless such persons have at least been promised naturalisation by Armenia.

4. After the Requested Member State has given a positive reply to the readmission application, the competent diplomatic or consular representation of that Member State shall, irrespective of the will of the person to be readmitted, immediately, free of charge and not later than within three working days, issue the travel document required for the return of the person to be readmitted with a period of validity of 120 days.

5. If, for legal or factual reasons, the person concerned cannot be transferred within the period of validity of the travel document that was initially issued, the competent diplomatic or consular representation of that Member State shall, within three working days and free of charge, issue a new travel document with a period of validity of the same duration.

Article 6

Readmission of third-country nationals and stateless persons

1. A Member State shall readmit, upon application by Armenia and without further formalities other than those provided for in this Agreement, all third-country nationals or stateless persons who do not, or who no longer, fulfil the conditions in force for entry to, presence in, or residence on, the territory of Armenia provided that it is proved, or may be validly assumed on the basis of prima facie evidence furnished, that such persons:

- (a) hold at the time of submission of the readmission application a valid visa or residence permit issued by the Requested Member State; or
- (b) illegally and directly entered the territory of Armenia after having stayed on, or transited through, the territory of the Requested Member State.

2. The readmission obligation in paragraph 1 shall not apply if the third country national or stateless person has only been in airside transit via an international airport of the Requested Member State.

3. The readmission obligation in paragraph 1 is for the Member State that issued a visa or residence permit. If two or more Member States issued a visa or residence permit, the readmission obligation in paragraph 1 is for the Member State that issued the document with a longer period of validity or, if one or several of them have already expired, the document that is still valid. If all of the documents have already expired, the readmission obligation in paragraph 1 is for the Member State that issued the document with the most recent expiry date. If no such documents can be presented, the readmission obligation in paragraph 1 is for the Member State of last exit.

4. Without prejudice to Article 7(2), after the Member State has given a positive reply to the readmission application, Armenia issues to the person whose readmission has been accepted the travel document required for his or her return.

SECTION III

READMISSION PROCEDURE

Article 7

Principles

1. Subject to paragraph 2, any transfer of a person to be readmitted on the basis of one of the obligations contained in Articles 3 to 6 shall require the submission of a readmission application to the competent authority of the Requested State.

2. If the person to be readmitted is in possession of a valid travel document or identity card and, in the case of third country nationals or stateless persons, a valid visa or residence permit of the Requested State, the transfer of

⁽³⁾ Ibid.

such person can take place without the Requesting State having to submit a readmission application or written notification referred to in Article 12(1) to the competent authority of the Requested State.

3. Without prejudice to paragraph 2, if a person has been apprehended in the border region, including airports, of the Requesting State after illegally crossing the border coming directly from the territory of the Requested State, the Requesting State may submit a readmission application within two working days following this person's apprehension (accelerated procedure).

Article 8

Readmission application

1. To the extent possible, the readmission application is to contain the following information:

- (a) the particulars of the person to be readmitted (e.g. given names, surnames, date of birth, and – where possible – place of birth, and the last place of residence) and, where applicable, the particulars of minor unmarried children and/or spouses;
- (b) in case of own nationals, indication of the means with which proof or *prima facie* evidence of nationality as set out by Annexes 1 and 2 respectively will be provided;
- (c) in case of third country nationals and stateless persons, indication of the means with which proof or *prima facie* evidence of the conditions for the readmission of third-country nationals and stateless persons as provided for by Annexes 3 and 4 respectively will be provided;
- (d) photograph of the person to be readmitted.

2. To the extent possible, the readmission application shall also contain the following information:

- (a) a statement indicating that the person to be transferred may need help or care, provided the person concerned has explicitly consented to the statement;
- (b) any other protection, security measure or information concerning the health of the person, which may be necessary in the individual transfer case.

3. A common form to be used for readmission applications is attached as Annex 5 to this Agreement.

4. A readmission application may be submitted by any means of communication including electronic ones.

Article 9

Means of evidence regarding nationality

1. Proof of nationality pursuant to Article 3(1) and Article 5(1) can be particularly furnished through the documents listed in Annex 1 to this Agreement, including documents the validity of which has expired by up to six months. If such documents are presented, the Member States and Armenia shall mutually recognise the nationality without further investigation being required. Proof of nationality cannot be furnished through false documents.

2. *Prima facie* evidence of nationality pursuant to Article 3(1) and Article 5(1) can be particularly furnished through the documents listed in Annex 2 to this Agreement, even if their period of validity has expired. If such documents are presented, the Member States and Armenia shall deem the nationality to be established, unless they can prove otherwise. *Prima facie* evidence of nationality cannot be furnished through false documents.

3. If none of the documents listed in Annexes 1 or 2 can be presented, the competent diplomatic or consular representations of the Requested State concerned shall, upon a request from the Requesting State which is to be included in the readmission application, interview the person to be readmitted without undue delay, at the latest within five working days from the date of receipt of the readmission application in accordance with Article 11(2), in order to establish his or her nationality. The procedure for such interviews may be established in the implementing Protocols provided for in Article 20 of this Agreement.

Article 10

Means of evidence regarding third-country nationals and stateless persons

1. Proof of the conditions for the readmission of third-country nationals and stateless persons laid down in Article 4(1) and Article 6(1) shall be particularly furnished through the means of evidence listed in Annex 3 to this Agreement; it cannot be furnished through false documents. Any such proof shall be mutually recognised by the Member States and Armenia without any further investigation being required.

2. *Prima facie* evidence of the conditions for the readmission of third-country nationals and stateless persons laid down in Article 4(1) and Article 6(1) shall be particularly furnished through the means of evidence listed in Annex 4 to this Agreement; it cannot be furnished through false documents. Where such *prima facie* evidence is presented, the Member States and Armenia shall deem the conditions to be established, unless they can prove otherwise.

3. The unlawfulness of entry, presence or residence shall be established by means of the travel documents of the person concerned in which the necessary visa or other residence permit for the territory of the Requesting State are

missing. A statement by the Requesting State that the person concerned has been found not having the necessary travel documents, visa or residence permit shall likewise provide *prima facie* evidence of the unlawful entry, presence or residence.

Article 11

Time limits

1. The application for readmission must be submitted to the competent authority of the Requested State within a maximum of nine months after the Requesting State's competent authority has gained knowledge that a third-country national or a stateless person does not, or does no longer, fulfil the conditions in force for entry, presence or residence. Where there are legal or factual obstacles to the application being submitted in time, the time limit shall, upon request by the Requesting State, be extended but only until the obstacles have ceased to exist.

2. A readmission application must be replied to in writing

— within two working days if the application has been made under the accelerated procedure (Article 7(3));

— within twelve calendar days in all other cases.

This time limit begins to run with the date of receipt of the readmission request. If there was no reply within this time limit, the transfer shall be deemed to have been agreed to.

Reply to a readmission application may be submitted by any means of communication including electronic ones.

3. Reasons for the refusal of a readmission request shall be given in writing.

4. After agreement has been given or, where appropriate, after expiry of the time limits laid down in paragraph 2, the person concerned shall be transferred within three months. On request of the Requesting State, this time limit may be extended by the time taken to deal with legal or practical obstacles.

Article 12

Transfer modalities and modes of transportation

1. Without prejudice to Article 7(2), before returning a person, the competent authorities of the Requesting State shall notify in writing at least two working days in advance the competent authorities of the Requested State regarding the transfer date, the point of entry, possible escorts and other information relevant to the transfer.

2. Transportation may take place by any means including by air. Return by air shall not be restricted to the use of the national carriers of Armenia or the Member States and may take place by using scheduled or charter flights. In the event

of escorted returns, such escorts shall not be restricted to authorised persons of the Requesting State, provided that they are persons authorised by Armenia or any Member State.

3. If the transfer takes place by air, possible escorts shall be exempted from having to obtain necessary visas.

Article 13

Readmission in error

The Requesting State shall take back any person readmitted by the Requested State if it is established, within a period of six months after the transfer of the person concerned, that the requirements laid down in Articles 3 to 6 of this Agreement are not met.

In such cases the procedural provisions of this Agreement shall apply *mutatis mutandis* and all available information relating to the actual identity and nationality of the person to be taken back shall be provided.

SECTION IV

TRANSIT OPERATIONS

Article 14

Principles

1. The Member States and Armenia should restrict the transit of third-country nationals or stateless persons to cases where such persons cannot be returned to the State of destination directly.

2. Armenia shall allow the transit of third-country nationals or stateless persons if a Member State so requests, and a Member State shall authorise the transit of third-country nationals or stateless persons if Armenia so requests, if the onward journey in possible other States of transit and the readmission by the State of destination is assured.

3. Transit can be refused by Armenia or a Member State:

(a) if the third-country national or the stateless person runs the real risk of being subjected to torture or to inhuman or degrading treatment or punishment or the death penalty or of persecution because of his race, religion, nationality, membership of a particular social group or political conviction in the State of destination or another State of transit; or

(b) if the third-country national or the stateless person shall be subject to criminal sanctions in the Requested State or in another State of transit; or

(c) on grounds of public health, domestic security, public order or other national interests of the Requested State.

4. Armenia or a Member State may revoke any authorisation issued if circumstances referred to in paragraph 3 subsequently arise or come to light which stand in the way of the transit operation, or if the onward journey in possible States of transit or the readmission by the State of destination is no longer assured. In this case, the Requesting State shall take back the third-country national or the stateless person, as necessary and without delay.

Article 15

Transit procedure

1. An application for transit operations must be submitted to the competent authority of the Requested State in writing and is to contain the following information:

- (a) type of transit (by air, sea or land), possible other States of transit and intended final destination;
- (b) the particulars of the person concerned (e.g. given name, surname, maiden name, other names used/by which known or aliases, date of birth, sex and – where possible – place of birth, nationality, language, type and number of travel document);
- (c) envisaged point of entry, time of transfer and possible use of escorts;
- (d) a declaration that in the view of the Requesting State the conditions pursuant to Article 14(2) are met, and that no reasons for a refusal pursuant to Article 14(3) are known of.

A common form to be used for transit applications is attached as Annex 6 to this Agreement.

A transit application may be submitted by any means of communication including electronic ones.

2. The Requested State shall, within three working days after receipt of the application and in writing, inform the Requesting State of the admission, confirming the point of entry and the envisaged time of admission, or inform it of the admission refusal and of the reasons for such refusal. If there was no reply within three working days, the transit shall be deemed to have been agreed to.

Reply to a transit application may be submitted by any means of communication including electronic ones.

3. If the transit operation takes place by air, the person to be readmitted and possible escorts shall be exempted from having to obtain an airport transit visa.

4. The competent authorities of the Requested State shall, subject to mutual consultations, assist in the transit operations, in particular through the surveillance of the persons in question and the provision of suitable amenities for that purpose.

5. Transit of the persons shall be carried out within 30 days of receipt of consent to the request.

SECTION V

COSTS

Article 16

Transport and transit costs

Without prejudice to the right of the competent authorities to recover the costs associated with the readmission from the person to be readmitted or third parties, all transport costs incurred in connection with readmission and transit operations pursuant to this Agreement as far as the border of the State of final destination shall be borne by the Requesting State.

SECTION VI

DATA PROTECTION AND RELATION TO OTHER INTERNATIONAL OBLIGATIONS

Article 17

Data protection

The communication of personal data shall only take place if such communication is necessary for the implementation of this Agreement by the competent authorities of Armenia or a Member State as the case may be. The processing and treatment of personal data in a particular case shall be subject to the domestic laws of Armenia and, where the controller is a competent authority of a Member State, to the provisions of Directive 95/46/EC and of the national legislation of that Member State adopted pursuant to that Directive. Additionally, the following principles shall apply:

- (a) personal data must be processed fairly and lawfully;
- (b) personal data must be collected for the specified, explicit and legitimate purpose of implementing this Agreement and not further processed by the communicating authority nor by the receiving authority in a way incompatible with that purpose;
- (c) personal data must be adequate, relevant and not excessive in relation to the purpose for which they are collected and/or further processed; in particular, personal data communicated may concern only the following:
 - the particulars of the person to be transferred (e.g. given names, surnames, any previous names, other names used/by which known or aliases, sex, civil status, date and place of birth, current and any previous nationality),
 - passport, identity card or driving licence (number, period of validity, date of issue, issuing authority, place of issue),

- stop-overs and itineraries,
 - other information needed to identify the person to be transferred or to examine the readmission requirements pursuant to this Agreement;
- (d) personal data must be accurate and, where necessary, kept up-to-date;
- (e) personal data must be kept in a form which permits identification of data subjects for no longer than is necessary for the purpose for which the data were collected or for which they are further processed;
- (f) both the communicating authority and the receiving authority shall take every reasonable step to ensure as appropriate the rectification, erasure or blocking of personal data where the processing does not comply with the provisions of this Article, in particular because those data are not adequate, relevant, accurate, or they are excessive in relation to the purpose of processing. This includes the notification of any rectification, erasure or blocking to the other Party;
- (g) upon request, the receiving authority shall inform the communicating authority of the use of the communicated data and of the results obtained therefrom;
- (h) personal data may only be communicated to the competent authorities. Further communication to other bodies requires the prior consent of the communicating authority;
- (i) the communicating and the receiving authorities are under an obligation to make a written record of the communication and receipt of personal data.

Article 18

Relation to other international obligations

1. This Agreement shall be without prejudice to the rights, obligations and responsibilities of the Union, its Member States and Armenia arising from international law including from international conventions to which they are party, in particular from the international instruments listed in Article 2 and:

- the international conventions determining the State responsible for examining applications for asylum lodged,
- international conventions on extradition and transit,
- multilateral international conventions and agreements on the readmission of foreign nationals.

2. Nothing in this Agreement shall prevent the return of a person under other formal or informal arrangements.

SECTION VII

IMPLEMENTATION AND APPLICATION

Article 19

Joint readmission committee

1. The Contracting Parties shall provide each other with mutual assistance in the application and interpretation of this Agreement. To this end, they shall set up a joint readmission committee (hereinafter referred to as 'the committee') which will, in particular, have the task:

- (a) to monitor, and exchange information regarding, the application of this Agreement, excluding personal data;
- (b) to address issues arising out of the interpretation or application of the provisions of this Agreement;
- (c) to decide on implementing arrangements necessary for the uniform application of this Agreement;
- (d) to have regular exchanges of information on the implementing Protocols drawn up by individual Member States and Armenia pursuant to Article 20;
- (e) to recommend amendments to this Agreement and its Annexes.

2. The decisions of the committee shall be binding on the Contracting Parties.

3. The committee shall be composed of representatives of the Union and Armenia.

4. The committee shall meet where necessary at the request of one of the Contracting Parties.

5. The committee shall establish its rules of procedures.

Article 20

Implementing Protocols

1. Without prejudice to the direct applicability of the present Agreement, on request of a Member State or Armenia, Armenia and a Member State shall draw up an implementing Protocol which shall, inter alia, cover:

- (a) designation of the competent authorities, border crossing points and exchange of contact points;
- (b) conditions for escorted returns, including the transit of third-country nationals and stateless persons under escort;
- (c) means and documents additional to those listed in the Annexes 1 to 4 to this Agreement;

(d) the modalities for readmission under the accelerated procedure;

(e) the procedure for interviews.

2. The implementing Protocols referred to in paragraph 1 shall enter into force only after the joint readmission committee referred to in Article 19 has been notified.

3. Armenia agrees to apply any provision of an implementing Protocol drawn up with one Member State also in its relations with any other Member State upon request of the latter. The Member States agree to apply any provision of an implementing Protocol concluded by one of them also in their relations with Armenia upon request of the latter, subject to the practical feasibility of its application to other Member States.

Article 21

Relation to bilateral readmission agreements or arrangements of Member States

The provisions of this Agreement shall take precedence over the provisions of any bilateral agreement or arrangement on the readmission of persons residing without authorisation which have been or may, under Article 20, be concluded between individual Member States and Armenia, in so far as the provisions of the latter are incompatible with those of this Agreement.

SECTION VIII

FINAL PROVISIONS

Article 22

Territorial application

1. Subject to paragraph 2, this Agreement shall apply to the territory in which the Treaty on European Union and the Treaty on the Functioning of the European Union are applicable and to the territory of Armenia.

2. This Agreement shall apply to the territory of the United Kingdom of Great Britain and Northern Ireland and of Ireland only pursuant to a notification by the European Union to Armenia to that effect. This Agreement shall not apply to the territory of the Kingdom of Denmark.

Article 23

Entry into force, duration and termination

1. This Agreement shall be ratified or approved by the Contracting Parties in accordance with their respective procedures.

2. This Agreement shall enter into force on the first day of the second month following the date on which the last Contracting Party has notified the other that the procedures referred to in paragraph 1 have been completed.

3. This Agreement shall apply to the United Kingdom of Great Britain and Northern Ireland and to Ireland on the first day of the second month following the date of the notification referred to in Article 22(2).

4. The Agreement is concluded for an unlimited period.

5. This Agreement may be amended by mutual consent of the Contracting Parties. Amendments shall be drawn up in the form of separate protocols, which shall form an integral part of this Agreement, and enter into force in accordance with the procedure laid down in this Article.

6. Each Contracting Party may, by officially notifying the other Contracting Party and after prior consultation of the committee referred to in Article 19, completely or partly, temporarily suspend the implementation of this Agreement. The suspension shall enter into force on the second day following the day of such notification.

7. Each Contracting Party may terminate this Agreement by officially notifying the other Contracting Party. This Agreement shall cease to apply six months after the date of such notification.

Article 24

Annexes

Annexes 1 to 6 shall form an integral part of this Agreement.

Done at Brussels on the nineteenth day of April in the year two thousand and thirteen in duplicate in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Armenian languages, each of these texts being equally authentic.

За Европейския съюз
 Por la Unión Europea
 За 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 Sąjungos vardu
 Az Európai Unió részéről
 Ghall-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
 Եվրոպական Միության կողմից




За Република Армения
 Por la República de Armenia
 За Армénskou republiku
 For Republikken Armenien
 Für die Republik Armenien
 Armeenia Vabariigi nimel
 Για της Δημοκρατίας της Αρμενίας
 For the Republic of Armenia
 Pour la République d'Arménie
 Per la Repubblica di Armenia
 Armēnijas Republikas vārdā –
 Armēnijos Respublikos vardu
 Örmény Köztársaság részéről
 Ghall-Repubblika tal-Armenja
 Voor de Republiek Armenië
 W imieniu Republiki Armenii
 Pela República da Arménia
 Pentru Republica Armenia
 Za Arménsku republiku
 Za Republiko Armenijo
 Armenian tasavallan puolesta
 För Republiken Armenien
 Հայաստանի Հանրապետության կողմից



ANNEX 1

COMMON LIST OF DOCUMENTS, THE PRESENTATION OF WHICH IS CONSIDERED AS PROOF OF NATIONALITY

(Articles 3(1), 5(1) and 9(1))

- passports of any kind (national passports, diplomatic passports, service passports, collective passports and surrogate passports including children's passports),
- identity cards of any kind (including temporary and provisional ones),
- citizenship certificates and other official documents that mention or clearly indicate citizenship.

ANNEX 2

COMMON LIST OF DOCUMENTS, THE PRESENTATION OF WHICH IS CONSIDERED AS PRIMA FACIE EVIDENCE OF NATIONALITY

(Articles 3(1), 5(1) and 9(2))

- documents listed in Annex 1, the validity of which has expired by more than six months,
- photocopies of any of the documents listed in Annex 1 to this Agreement,
- driving licenses or photocopies thereof,
- birth certificates or photocopies thereof,
- company identity cards or photocopies thereof,
- statements by witnesses,
- statements made by the person concerned and language spoken by him or her, including by means of an official test result,
- any other document which may help to establish the nationality of the person concerned,
- fingerprints,
- *laissez-passer* issued by the Requested State,
- service books and military identity cards,
- seaman's registration books and skippers' service cards,
- confirmation of identity as a result of a search carried out in the Visa Information System ⁽¹⁾,
- in the case of Member States not using the Visa Information System, positive identification established from visa application records of those Member States.

⁽¹⁾ Regulation (EC) No 767/2008 of the European Parliament and of the Council of 9 July 2008 concerning the Visa Information System (VIS) and the exchange of data between Member States on short-stay visas (VIS Regulation) (OJ L 218, 13.8.2008, p. 60).

ANNEX 3

COMMON LIST OF DOCUMENTS WHICH ARE CONSIDERED AS PROOF OF THE CONDITIONS FOR THE READMISSION OF THIRD-COUNTRY NATIONALS AND STATELESS PERSONS

(Articles 4(1), 6(1) and 10(1))

- visa and/or residence permit issued by the Requested State,
- entry/departure stamps or similar endorsement in the travel document of the person concerned or other evidence of entry/departure (e.g. photographic).

ANNEX 4

COMMON LIST OF DOCUMENTS WHICH ARE CONSIDERED AS PRIMA FACIE EVIDENCE OF THE CONDITIONS FOR THE READMISSION OF THIRD-COUNTRY NATIONALS AND STATELESS PERSONS

(Articles 4(1), 6(1) and 10(2))

- description issued by the relevant authorities of the Requesting State, of place and circumstances under which the person concerned has been intercepted after entering the territory of that State,
- information related to the identity and/or stay of a person which has been provided by an international organisation (e.g. UNHCR),
- reports/confirmation of information by family members, travelling companions, etc.;
- statement by the person concerned,
- fingerprints,
- documents, certificates and bills of any kind (e.g. hotel bills, appointment cards for doctors/dentists, entry cards for public/private institutions, car rental agreements, credit card receipts etc.) which clearly show that the person concerned stayed on the territory of the Requested State,
- named tickets and/or passenger lists of air, train, coach or boat passages which show the presence and the itinerary of the person concerned on the territory of the Requested State,
- information showing that the person concerned has used the services of a courier or travel agency,
- official statements made, in particular, by border authority staff and other witnesses who can testify to the person concerned crossing the border,
- official statement by the person concerned in judicial or administrative proceedings.

ANNEX 5



[Emblem of the Republic of Armenia]

.....
 (Place and date)

 (Designation of requesting authority)

Reference:

To

.....

 (Designation of requested authority)

☐ ACCELERATED PROCEDURE (Article 7(3))☐ INTERVIEW REQUEST (Article 9(3))

READMISSION APPLICATION

pursuant to Article 8 of the Agreement of between the European Union and the Republic of
 Armenia on the readmission of persons residing without authorisation

A. PERSONAL DETAILS

1. Full name (underline surname):

.....

2. Maiden name:

.....

3. Date and place of birth:

.....

4. Sex and physical description (height, colour of eyes, distinguishing marks etc.):

.....

5. Also known as (earlier names, other names used/by which known or aliases):

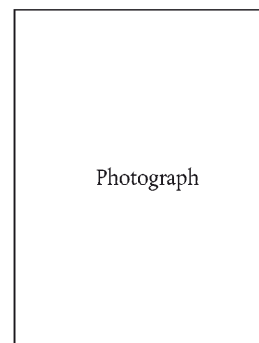
.....

6. Nationality and language:

.....

7. Civil status: ☐ married ☐ single ☐ divorced ☐ widowed

If married: name of spouse



Names and age of children (if any)

.....

.....

.....

8. Last address in the Requested State:

.....

B. PERSONAL DETAILS OF SPOUSE (IF APPROPRIATE)

1. Full name (underline surname):

.....

2. Maiden name:

.....

3. Date and place of birth:

.....

4. Sex and physical description (height, color of eyes, distinguishing marks etc.):

.....

5. Also known as (earlier names, other names used/by which known or aliases):

.....

6. Nationality and language:

.....

C. PERSONAL DETAILS OF CHILDREN (IF APPROPRIATE)

1. Full name (underline surname):

.....

2. Date and place of birth:

.....

3. Sex and physical description (height, colour of eyes, distinguishing marks etc.):

.....

4. Nationality and language:

.....

D. SPECIAL CIRCUMSTANCES RELATING TO THE TRANSFEREE

1. State of health

(e.g. possible reference to special medical care; Latin name of contagious disease):

.....

2. Indication of particularly dangerous person

(e.g. suspected of serious offence; aggressive behaviour):

.....

E. MEANS OF EVIDENCE ATTACHED

1.

(Passport No)

.....

(date and place of issue)

.....

(issuing authority)

.....

(expiry date)

2.	 (Identity card No)	 (date and place of issue)
	 (issuing authority)	 (expiry date)
3.	 (Driving licence No)	 (date and place of issue)
	 (issuing authority)	 (expiry date)
4.	 (Other official document No)	 (date and place of issue)
	 (issuing authority)	 (expiry date)

F. OBSERVATIONS

.....
.....
.....

.....
(Signature) (Seal/stamp)

ANNEX 6



[Emblem of the Republic of Armenia]

.....
 (Place and date)

 (Designation of requesting authority)

Reference

.....
 To

 (Designation of requested authority)

TRANSIT APPLICATION

pursuant to Article 15 of the Agreement of between the European Union and the Republic of Armenia on the readmission of persons residing without authorisation

A. PERSONAL DETAILS

1. Full name (underline surname):

.....

2. Maiden name:

.....

3. Date and place of birth:

.....

4. Sex and physical description (height, colour of eyes, distinguishing marks etc.):

.....

5. Also known as (earlier names, other names used/by which known or aliases):

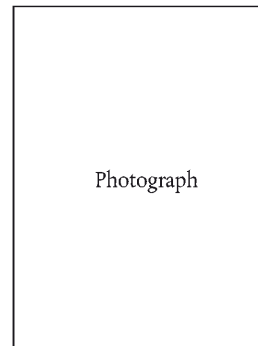
.....

6. Nationality and language:

.....

7. Type and number of travel document:

.....



B. TRANSIT OPERATION

1. Type of transit

☐ by air☐ by land☐ by sea

2. State of final destination

.....

3. Possible other States of transit

.....

4. Proposed border crossing point, date, time of transfer and possible escorts

.....

.....

.....

5. Admission guaranteed in any other transit State and in the State of final destination

(Article 13, paragraph 2)

☐ yes

☐ no

6. Knowledge of any reason for a refusal of transit

(Article 13, paragraph 3)

☐ yes

☐ no

C. OBSERVATIONS

.....

.....

.....

.....

.....

(Signature) (Seal/stamp)

Joint declaration concerning articles 3(3) and 5(3)

The Contracting Parties take note that, according to the nationality laws of the Republic of Armenia and the Member States, it is not possible for a citizen of the Republic of Armenia or the European Union to be deprived of his or her nationality.

The Parties agree to consult each other in due time should this legal situation change.

Joint Declaration Concerning the Republic of Iceland

The Contracting Parties take note of the close relationship between the European Union and the Republic of Iceland, particularly by virtue of the Agreement of 18 May 1999 concerning the association of this country with the implementation, application and development of the Schengen *acquis*. In such circumstances it is appropriate that Armenia conclude a readmission agreement with the Republic of Iceland on the same terms as this Agreement.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 1059/2013

of 29 October 2013

concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for cattle for fattening and amending Regulation (EC) No 492/2006 (holder of the authorisation Prosol SpA)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

cows and horses by Commission Regulation (EU) No 1119/2010 ⁽⁵⁾, and for weaned piglets by Commission Regulation (EU) No 170/2011 ⁽⁶⁾.

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) A preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on cattle for fattening by Commission Regulation (EC) No 492/2006 ⁽³⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was also authorised for 10 years for sows by Commission Regulation (EC) No 896/2009 ⁽⁴⁾, for dairy

- (4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of that preparation as a feed additive for cattle for fattening, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 March 2013 ⁽⁷⁾ that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect on animal health, human health or the environment and it has the potential to improve the final body weight, the feed to gain ratio and the average daily gain. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) The assessment of the preparation of *Saccharomyces cerevisiae* MUCL 39885 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 492/2006 of 27 March 2006 concerning the provisional and permanent authorisation of certain additives in feedingstuffs (OJ L 89, 28.3.2006, p. 6).

⁽⁴⁾ Commission Regulation (EC) No 896/2009 of 25 September 2009 concerning the authorisation of a new use of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows (holder of the authorisation Prosol SpA) (OJ L 256, 29.9.2009, p. 6).

⁽⁵⁾ Commission Regulation (EU) No 1119/2010 of 2 December 2010 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and amending Regulation (EC) No 1520/2007 (holder of the authorisation Prosol SpA) (OJ L 317, 3.12.2010, p. 9).

⁽⁶⁾ Commission Regulation (EU) No 170/2011 of 23 February 2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA) (OJ L 49, 24.2.2011, p. 8).

⁽⁷⁾ EFSA Journal 2013; 11(4):3174.

- (7) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on *Saccharomyces cerevisiae* MUCL 39885 contained in Regulation (EC) No 492/2006 should be deleted. Regulation (EC) No 492/2006 should therefore be amended accordingly.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional

group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

In Annex II to Regulation (EC) No 492/2006 the entry on E 1710, *Saccharomyces cerevisiae* MUCL 39 885 is deleted.

Article 3

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 19 May 2014 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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

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

Done at Brussels, 29 October 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1710	Prosol SpA	<i>Saccharomyces cerevisiae</i> MUCL 39885	<i>Additive composition</i> Preparation of <i>Saccharomyces cerevisiae</i> MUCL 39885 containing a minimum of: Powder: 1 × 10 ⁹ CFU/g of additive Solid form <i>Characterisation of the active substance</i> Viable cells of <i>Saccharomyces cerevisiae</i> MUCL 39885 <i>Analytical method</i> ⁽¹⁾ Enumeration: pour plate method using chloramphenicol glucose yeast extract agar (EN15789:2009) Identification: polymerase chain reaction (PCR) method	Cattle for fattening	—	4 × 10 ⁹	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. Minimum recommended content of additive for head per day: 3,6 × 10 ¹⁰ CFU. 3. For safety: glasses and gloves shall be used during handling.	19 November 2023

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 1060/2013
of 29 October 2013
concerning the authorisation of bentonite as a feed additive for all animal species
(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.
- (2) Bentonite was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive belonging to the group of binders, anticaking agents and coagulants, for use in all animal species, by Commission Directive 82/822/EEC⁽³⁾. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of bentonite as a feed additive for all animal species as binders and anticaking agents and, in accordance with Article 7 of that Regulation, for a new authorisation as substance for control of radionuclide contamination, for all animal species. In addition, in accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new authorisation of

bentonite as substance for reduction of the contamination of feed by mycotoxins for all animal species. Those applications request that additive to be classified in the additive category 'technological additives' and were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 2 February 2011⁽⁴⁾, 14 June 2011⁽⁵⁾ and 14 June 2012⁽⁶⁾ that, under the proposed conditions of use, bentonite does not have an adverse effect on animal health, human health or the environment, and that it has the potential to be efficacious as binder and anticaking agent and as substance for control of radionuclide contamination for all animal species. It was also recognised that bentonite has the potential to be efficacious as aflatoxin binder for dairy cows and that this conclusion can be extended to all ruminants. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) Since the provided *in vitro* studies meet the conditions for the demonstration of the efficacy of the technological additives laid down by Commission Regulation (EC) No 429/2008⁽⁷⁾, in particular under item 4 of Annex II and under item 1.4 of Annex III thereto, and they were recognised able to demonstrate the clear evidence to bind aflatoxin B1 (AfB) and moreover the binding capacity, restricted to aflatoxin B1, was defined as a characteristic of the bentonite, the conclusion on efficacy as a substance for reduction of the contamination of feed by mycotoxins can be considered sufficient to be extended to its use on poultry and pigs.
- (6) The assessment of bentonite shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised as specified in the Annexes to this Regulation.

⁽⁴⁾ EFSA Journal 2011; 9(2):2007.

⁽⁵⁾ EFSA Journal 2011; 9(6):2276.

⁽⁶⁾ EFSA Journal 2012; 10(7):2787.

⁽⁷⁾ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Forty-first Commission Directive 82/822/EEC of 19 November 1982 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (OJ L 347, 7.12.1982, p. 16).

- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of bentonite as binder and anticaking agent, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Bentonite specified in the Annexes, belonging to the additive category 'technological additives' and to the functional groups 'substances for reduction of the contamination of feed by

mycotoxins', 'binders', 'anticaking agents' and 'substances for control of radionuclide contamination' is authorised as an additive in animal nutrition, subject to the conditions laid down in those Annexes.

Article 2

The additive specified in Annex II belonging to the functional groups 'binders' and 'anticaking agents' and feed containing that additive, which are produced and labelled before 19 November 2015 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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

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

Done at Brussels, 29 October 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			

Category of technological additives. Functional group: substances for reduction of the contamination of feed by mycotoxins: aflatoxin B1

1m558	Bentonite	<i>Additive composition</i>	Ruminants	—		20 000	1. Indicate in the instructions for use: — 'The simultaneous oral use with macrolides shall be avoided'; — for poultry: 'The simultaneous use with robenidine shall be avoided'. 2. For poultry: the simultaneous use with coccidiostats other than robenidine is contraindicated with level of bentonite above 5 000 mg/kg of complete feed. 3. The total amount of bentonite must not exceed the permitted maximum level in complete feedingstuff of 20 000 mg/kg of complete feedingstuff. 4. The use of the additive is allowed in feedingstuffs complying with the European Union legislation on undesirable substances in animal feed. 5. For safety: breathing protection, glasses and gloves shall be used during handling.	19 November 2023
		Bentonite: ≥ 70 % smectite (dioctahedral montmorillonite) <i>Characterisation of active substance</i> Bentonite: ≥ 70 % smectite (dioctahedral montmorillonite) < 10 % opal and feldspar < 4 % quartz and calcite Afb ₁ -binding capacity (BC _{Afb1}) above 90 % <i>Analytical method</i> ⁽¹⁾ For the determination of bentonite in feed additive: X-ray diffraction (XRD) For the determination of BC _{Afb1} of the additive: adsorption test carried out in a buffer solution at pH 5,0 with a concentration of 4 mg/l for Afb ₁ and 0,02 % (w/v) for the feed additive.	Poultry Pigs					

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

ANNEX II

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: binders								
1m558i	Bentonite	<i>Additive composition</i> Bentonite: ≥ 50 % smectite <i>Characterisation of active substance</i> Bentonite: ≥ 50 % smectite <i>Analytical method ⁽¹⁾</i> For the determination in feed additive: X-ray diffraction (XRD)	All animal species	—		20 000	1. Indicate in the instructions for use: — ‘The simultaneous oral use with macrolides shall be avoided’; — in poultry: ‘The simultaneous use with robenidine shall be avoided’. 2. For poultry: the simultaneous use with coccidiostats other than robenidine is contraindicated with level of bentonite above 5 000 mg/kg of complete feed. 3. The total amount of bentonite must not exceed the permitted maximum level in complete feedingstuff of 20 000 mg/kg of complete feedingstuff. 4. For safety: breathing protection, glasses and gloves shall be used during handling.	19 November 2023
Category of technological additives. Functional group: anticaking agents								
1m558i	Bentonite	<i>Additive composition</i> Bentonite: ≥ 50 % smectite <i>Characterisation of active substance</i> Bentonite: ≥ 50 % smectite <i>Analytical method ⁽¹⁾</i> For the determination in feed additive: X-ray diffraction (XRD)	All animal species	—		20 000	1. Indicate in the instructions for use: — ‘The simultaneous oral use with macrolides shall be avoided’; — in poultry: ‘The simultaneous use with robenidine shall be avoided’.	19 November 2023

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
							2. For poultry: the simultaneous use with coccidiostats other than robenidine is contraindicated with level of bentonite above 5 000 mg/kg of complete feed. 3. The total amount of bentonite must not exceed the permitted maximum level in complete feedingstuff of 20 000 mg/kg of complete feedingstuff. 4. For safety: breathing protection, glasses and gloves shall be used during handling.	
Category of technological additives. Functional group: substances for control of radionuclide contamination (^{134/137} Cs)								
1m558i	Bentonite	Additive composition Bentonite: ≥ 50 % smectite Characterisation of active substance Bentonite: ≥ 50 % smectite Analytical method ⁽¹⁾ For the determination in feed additive: X-ray diffraction (XRD)	All animal species	—		—	1. Indicate in the instructions for use: — ‘The simultaneous oral use with macrolides shall be avoided’; — in poultry: ‘The simultaneous use with robenidine shall be avoided’. 2. For poultry: the simultaneous use with coccidiostats other than robenidine is contraindicated with level of bentonite above 5 000 mg/kg of complete feed. 3. The mixture of different sources of bentonite must not exceed the permitted maximum level in complete feedingstuff of 20 000 mg/kg of complete feedingstuff. 4. The additive may be used where feed is contaminated by radiocaesium to control it in animals and their products. 5. For safety: breathing protection, glasses and gloves shall be used during handling.	19 November 2023

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 1061/2013

of 29 October 2013

concerning the authorisation of a preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for calves, kids, cats and dogs and amending Regulation (EC) No 1288/2004 (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.
- (2) The preparation of *Enterococcus faecium* NCIMB 10415 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on calves by Commission Regulation (EC) No 1288/2004⁽³⁾, for sows by Commission Regulation (EC) No 1200/2005⁽⁴⁾, for piglets by Commission Regulation (EC) No 252/2006⁽⁵⁾, for pigs for fattening by Commission

Regulation (EC) No 943/2005⁽⁶⁾, and for cats and dogs by Commission Regulation (EC) No 102/2009⁽⁷⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

- (3) The preparation was also authorised for 10 years for chickens for fattening by Commission Implementing Regulation (EU) No 361/2011⁽⁸⁾.
- (4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for calves, cats and dogs and, in accordance with Article 7 of that Regulation, for a new use for kids, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 January 2013⁽⁹⁾ that, under the proposed conditions of use, the preparation of *Enterococcus faecium* NCIMB 10415 does not have an adverse effect on animal health, human health or the environment, and that its use increases final body weight and/or daily weight gain in calves for rearing and fattening and that can be extrapolated to kids for rearing and fattening. It also recognised that the preparation has a beneficial effect in dogs by increasing the intestinal or serum concentration of IgA. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 1288/2004 of 14 July 2004 concerning the permanent authorisation of certain additives and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 243, 15.7.2004, p. 10).

⁽⁴⁾ Commission Regulation (EC) No 1200/2005 of 26 July 2005 concerning the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 195, 27.7.2005, p. 6).

⁽⁵⁾ Commission Regulation (EC) No 252/2006 of 14 February 2006 concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisations of new uses of certain additives already authorised in feedingstuffs (OJ L 44, 15.2.2006, p. 3).

⁽⁶⁾ Commission Regulation (EC) No 943/2005 of 21 June 2005 concerning the permanent authorisation of additives in feedingstuffs (OJ L 159, 22.6.2005, p. 6).

⁽⁷⁾ Commission Regulation (EC) No 102/2009 of 3 February 2009 concerning the permanent authorisation of an additive in feedingstuffs (OJ L 34, 4.2.2009, p. 8).

⁽⁸⁾ Commission Implementing Regulation (EU) No 361/2011 of 13 April 2011 concerning the authorisation of *Enterococcus faecium* NCIMB 10415 as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional products Ltd represented by DSM Nutritional Products Sp. Z o.o) and amending Regulation (EC) No 943/2005 (OJ L 100, 14.4.2011, p. 22).

⁽⁹⁾ EFSA Journal 2013; 11(2):3097 and 3098.

- (6) Since small but significant effects on faecal quality were observed in cats, it was considered sufficient to confirm the efficacy in this species.
- (7) The assessment of the preparation of *Enterococcus faecium* NCIMB 10415 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.
- (8) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 102/2009 should be repealed and Regulation (EC) No 1288/2004 should be amended accordingly.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional groups 'gut flora stabilisers' and 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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

Done at Brussels, 29 October 2013.

Article 2

Repeal of Regulation (EC) No 102/2009

Regulation (EC) No 102/2009 is repealed.

Article 3

Amendment to Regulation (EC) No 1288/2004

In Annex I to Regulation (EC) No 1288/2004 the entry on E 1705, *Enterococcus faecium* NCIMB 10415 is deleted.

Article 4

Transitional measures

The preparation specified in Annex as far as its use for calves is concerned, and feed containing that preparation, which are produced and labelled before 19 May 2014 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

The preparation specified in Annex as far as its use for cats and dogs is concerned, and feed containing that preparation, which are produced and labelled before 19 November 2015 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

Entry into force

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

For the Commission

The President

José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1705	DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o	<i>Enterococcus faecium</i> NCIMB 10415	<i>Additive composition</i> <i>Preparation of Enterococcus faecium</i> NCIMB 10415 containing a minimum of: micro-encapsulated form with shellac and other micro-encapsulated forms: 1 × 10 ¹⁰ CFU/g additive; non-coated granulated forms: 3,5 × 10 ¹⁰ CFU/g additive <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> NCIMB 10415 <i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)	Calves Kids	—	1 × 10 ⁹	—	In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.	19 November 2023
4b1705	DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o	<i>Enterococcus faecium</i> NCIMB 10415	<i>Additive composition</i> <i>Preparation of Enterococcus faecium</i> NCIMB 10415 containing a minimum of: 5 × 10 ⁹ CFU/g of additive; Microencapsulated forms (shellac). <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> NCIMB 10415	Cats	—	7 × 10 ⁹	—	In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.	19 November 2023

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
			<i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)						

Category of zootechnical additives. Functional group: other zootechnical additives (improvement of gut conditions)

4b1705	DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o	<i>Enterococcus faecium</i> NCIMB 10415	<i>Additive composition</i> Preparation of <i>Enterococcus faecium</i> NCIMB 10415 containing a minimum of 5×10^9 CFU/g of additive. Microencapsulated forms (shellac). <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> NCIMB 10415 <i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)	Dogs	—	$2,5 \times 10^9$		In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.	19 November 2023
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⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

COMMISSION IMPLEMENTING REGULATION (EU) No 1062/2013**of 30 October 2013****on the format of the European Technical Assessment for construction products**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC ⁽¹⁾, and in particular Article 26(3) thereof,

After consulting the Standing Committee on Construction,

Whereas:

- (1) European Technical Assessment is necessary to enable a manufacturer of a construction product to draw up a declaration of performance for a construction product which is not covered or not fully covered by a harmonised standard.
- (2) Article 26(2) of Regulation (EU) No 305/2011 establishes requirements for the content of the European Technical Assessment. Since the principles for the applicable factory production control shall be set out in the respective European Assessment Document (EAD), the European Technical Assessment should contain only such technical details as deemed necessary in these principles within the EAD to be defined at that level for the implementation of the system of assessment and verification of constancy of performance.
- (3) The presentation of the technical description of the product in question should be defined flexibly enough in the format of the European Technical Assessment, given the wide variety of construction products concerned.
- (4) Sufficient flexibility should also be allowed for the presentation of the performance of the product in the European Technical Assessment, to enable the manufacturer to declare fluently and accurately such performance in his declaration of performance which is based on that assessment.
- (5) In order to protect confidential technical information on the product, the manufacturer should be able to indicate to the responsible Technical Assessment Body which parts of the product description is confidential and may not be disclosed together with the European Technical Assessment. Confidential information should be included in separate Annexes to those European Technical Assessments.
- (6) In order to enhance the efficiency of the Internal Market and competitiveness of the European construction sector as a whole, European Technical Assessments should be able to be issued as soon as possible for manufacturers requesting them.

HAS ADOPTED THIS REGULATION:

Article 1

The format of the European Technical Assessment is set out in the Annex.

Article 2

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

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

Done at Brussels, 30 October 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 88, 4.4.2011, p. 5.

ANNEX

EUROPEAN TECHNICAL ASSESSMENT

No of [date]

General part

1. Technical Assessment Body issuing the European Technical Assessment:
.....
2. Trade name of the construction product:
.....
3. Product family to which the construction product belongs:
.....
4. Manufacturer:
.....
5. Manufacturing plant(s):
.....
6. This European Technical Assessment contains pages including Annex(es) which form an integral part of this assessment.
Annex(es) contain(s) confidential information and is/are not included in the European Technical Assessment when that assessment is publicly disseminated.
7. This European Technical Assessment is issued in accordance with Regulation (EU) No 305/2011, on the basis of

Specific parts

8. Technical description of the product:
.....
9. Specification of the intended use(s) in accordance with the applicable European Assessment Document (hereinafter EAD):
.....
10. Performance of the product and references to the methods used for its assessment:
.....
11. Assessment and verification of constancy of performance (hereinafter AVCP) system applied, with reference to its legal base:
.....
12. Technical details necessary for the implementation of the AVCP system, as provided for in the applicable EAD:
.....Issued in on/..... 20....
by
Annex(es)

COMMISSION IMPLEMENTING REGULATION (EU) No 1063/2013**of 30 October 2013****amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code as regards the use of the equivalence system in the sugar sector**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽¹⁾, and in particular Article 247 thereof,

Whereas:

- (1) Point 3 of Annex 74 to Commission Regulation (EEC) No 2454/93 ⁽²⁾ allows the use of the equivalence system between raw cane sugar (CN code 1701 11 90) and raw beet sugar (CN code 1701 12 90) under the condition that compensating products falling within CN code 1701 99 10 (white sugar) are obtained.
- (2) However, point 3 of Annex 74 to Regulation (EEC) No 2454/93 cannot be applied correctly because there is no market for raw beet sugar in the Union.
- (3) A solution should be found which ensures legal certainty in the sugar sector in connection with the use of equivalent goods.
- (4) White sugar is usually obtained from sugar beet in a continuous process. Raw beet sugar is not produced as a separate product during that process and therefore cannot be marketed. For that reason, it is desirable to allow the use of sugar beet instead of raw beet sugar as equivalent goods.
- (5) The yield of raw cane sugar should be calculated in accordance with point III(3) of Part B of Annex IV to Council Regulation (EC) No 1234/2007 ⁽³⁾ because this is a specific calculation method in the sugar sector.
- (6) The references to the Combined Nomenclature (CN) codes in point 3 of Annex 74 to Regulation (EEC) No 2454/93 should be updated because of the changes in the CN.

⁽¹⁾ OJ L 302, 19.10.1992, p. 1.

⁽²⁾ Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (OJ L 253, 11.10.1993, p. 1).

⁽³⁾ 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) (OJ L 299, 16.11.2007, p. 1).

- (7) Point 3 of Annex 74 to Regulation (EEC) No 2454/93 should therefore be amended accordingly.

- (8) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Point 3 of Annex 74 to Regulation (EEC) No 2454/93 is replaced by the following:

‘3. Sugar

Recourse to the use of equivalent goods is permitted between non-Union raw cane sugar (CN codes 1701 13 90 and/or 1701 14 90) and sugar beet (CN code 1212 91 80) under the condition that compensating products falling within CN code 1701 99 10 (white sugar) are obtained.

The equivalent quantity of raw cane sugar of standard quality as defined in point III of Part B of Annex IV to Council Regulation (EC) No 1234/2007 ^(*) shall be calculated by multiplying the quantity of white sugar with the coefficient 1,0869565.

The equivalent quantity of raw cane sugar not of standard quality shall be calculated by multiplying the quantity of white sugar with a coefficient obtained by dividing 100 by the yield of raw cane sugar. The yield of raw cane sugar shall be calculated as set out in point III (3) of part B of Annex IV to Regulation (EC) No 1234/2007.

^(*) 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) (OJ L 299, 16.11.2007, p. 1).’

Article 2

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

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

Done at Brussels, 30 October 2013.

For the Commission
The President
José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 1064/2013**of 30 October 2013****fixing the coefficients applicable to cereals exported in the form of Scotch whisky for the period 2013/2014**

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 1670/2006 of 10 November 2006 laying down certain detailed rules for the application of Council Regulation (EC) No 1784/2003 as regards the fixing and granting of adjusted refunds in respect of cereals exported in the form of certain spirit drinks ⁽²⁾, and in particular Article 5 thereof,

Whereas:

- (1) Article 4(1) of Regulation (EC) No 1670/2006 lays down that the quantities of cereals eligible for a refund are to be the quantities placed under control and distilled, weighted by a coefficient to be fixed annually for each Member State concerned. The coefficient is to express the ratio between the total quantities exported and the total quantities marketed of the spirit drink concerned, on the basis of the trend noted in those quantities during the number of years corresponding to the average ageing period of the spirit drink in question.
- (2) According to the information provided by the United Kingdom in respect of the period 1 January to 31 December 2012, the average ageing period for Scotch whisky in 2012 was seven years.

- (3) Commission Implementing Regulation (EU) No 745/2012 ⁽³⁾ has ceased to be operative given that it concerns the coefficients applicable for the year 2012/2013. The coefficients for the period 1 October 2013 to 30 September 2014 should therefore be fixed accordingly.

- (4) Article 10 of Protocol 3 to the Agreement on the European Economic Area excludes the granting of refunds in respect of exports to Liechtenstein, Iceland and Norway. Moreover, the Union has concluded agreements abolishing export refunds with certain third countries. Consequently, pursuant to Article 7(2) of Regulation (EC) No 1670/2006, this should be taken into account in calculating the coefficients for 2013/2014,

HAS ADOPTED THIS REGULATION:

Article 1

For the period 1 October 2013 to 30 September 2014, the coefficients provided for in Article 4 of Regulation (EC) No 1670/2006 applying to cereals used in the United Kingdom for producing Scotch whisky shall be as set out in the Annex to this Regulation.

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 1 October 2013 to 30 September 2014.

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

Done at Brussels, 30 October 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 312, 11.11.2006, p. 33.

⁽³⁾ Commission Implementing Regulation (EU) No 745/2012 of 16 August 2012 fixing the coefficients applicable to cereals exported in the form of Scotch whisky for the period 2012/2013 (OJ L 219, 17.8.2012, p. 13).

ANNEX

Coefficients applicable in the United Kingdom		
Period of application	Coefficient applicable	
	to malted barley used in the production of malt whisky	to cereals used in the production of grain whisky
From 1 October 2013 to 30 September 2014	0,667	0,515

COMMISSION REGULATION (EU) No 1065/2013

of 30 October 2013

amending Annex III to Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 ⁽¹⁾, and in particular Article 17(8) thereof,

Whereas:

- (1) The Republic of Peru has applied for the registration of 'Pisco' as a geographical indication in Annex III to Regulation (EC) No 110/2008, in accordance with the procedure laid down in Article 17(1) of that Regulation. 'Pisco' is a fruit spirit traditionally produced in Peru, from the fermentation and distillation of grapes.
- (2) The main specifications of the technical file for 'Pisco' were published in the *Official Journal of the European Union* ⁽²⁾ for the purposes of the objection procedure, pursuant to Article 17(6) of Regulation (EC) No 110/2008. As the Commission did not receive any objections in accordance with Article 17(7) of Regulation (EC) No 110/2008, that name should be included in Annex III to that Regulation.
- (3) According to the Agreement establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of

the other part, approved by Council Decision 2002/979/EC ⁽³⁾, 'Pisco' is a protected designation for spirit drinks originating in Chile. Therefore, it should be clarified that the protection of the geographical indication 'Pisco' for products originating in Peru does not hinder the use of such denomination for products originating in Chile.

- (4) Regulation (EC) No 110/2008 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Spirit Drinks,

HAS ADOPTED THIS REGULATION:

Article 1

In Annex III to Regulation (EC) No 110/2008, in product category '9. Fruit spirit', the following entry is added:

	'Pisco' (*)	Peru
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(*) The protection of the geographical indication "Pisco" under this Regulation shall be without prejudice to the use of the name "Pisco" for products originating in Chile protected under the Association Agreement between the Union and Chile of 2002.

Article 2

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

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

Done at Brussels, 30 October 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 39, 13.2.2008, p. 16.

⁽²⁾ OJ C 141, 12.5.2011, p. 16.

⁽³⁾ OJ L 352, 30.12.2002, p. 1.

COMMISSION REGULATION (EU) No 1066/2013

of 30 October 2013

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods⁽¹⁾, and in particular Article 18(5) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority' for a scientific assessment, as well as to the Commission and the Member States for information.
- (3) The Authority is to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Béres Pharmaceuticals Ltd, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of glucosamine and maintenance of joints (Question No EFSA-Q-2011-00907)⁽²⁾. The claim proposed by the applicant was worded as follows: 'Glucosamine contributes to the protection of joint cartilage exposed to excessive motion or loading and helps to improve the range of motion in joints'.
- (6) On 5 December 2011, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of glucosamine and the

claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

- (7) Following an application from Merck Consumer Healthcare, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of glucosamine and maintenance of normal joint cartilage (Question No EFSA-Q-2011-01113)⁽³⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Glucosamine contributes to the maintenance of normal joint cartilage'.
- (8) On 16 May 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of glucosamine and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (9) Following an application from Extraction Purification Innovation France, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the consumption of wheat polar lipid extract and protection of the skin against dehydration (Question No EFSA-Q-2011-01122)⁽⁴⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Contributes to improve skin hydration'.
- (10) On 5 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of wheat polar lipid extract and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (11) Following an application from Lesaffre International/Lesaffre Human Care, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of *Saccharomyces cerevisiae* var. *boulardii* CNCM I-3799 and reducing gastro-intestinal discomfort (Question No EFSA-Q-2012-00271)⁽⁵⁾. The claim proposed by the applicant was worded as follows: 'Saccharomyces cerevisiae var. *boulardii* CNCM I-3799 helps maintain intestinal comfort'.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.⁽²⁾ EFSA Journal 2011; 9(12):2476.⁽³⁾ EFSA Journal 2012; 10(5):2691.⁽⁴⁾ EFSA Journal 2012; 10(7):2773.⁽⁵⁾ EFSA Journal 2012; 10(7):2801.

- (12) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship could not be established between the consumption of *Saccharomyces cerevisiae* var. *boulardii* CNCM I-3799 and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (13) Following two applications from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and maintenance of normal hair (Question No EFSA-Q-2012-00334 and EFSA-Q-2012-00335) ⁽¹⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to increase hair number'.
- (14) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (*Cucurbita pepo* L.) and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (15) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of *Rhodiola rosea* L. extract and reduction of mental fatigue (Question No EFSA-Q-2012-00336) ⁽²⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to reduce tiredness in case of stress'.
- (16) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of *Rhodiola rosea* L. extract and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (17) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of flaxseed oil and vitamin E and maintenance of the skin permeability barrier function (Question No EFSA-Q-2012-00337) ⁽³⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Contributes to maintain skin permeability barrier function'.
- (18) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of flaxseed oil and vitamin E and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (19) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Opti_{EFAX}TM and maintenance of normal blood LDL-cholesterol concentrations (Question No EFSA-Q-2012-00339) ⁽⁴⁾. The claim proposed by the applicant was worded as follows: 'Opti_{EFAX}TM helps to maintain healthy blood levels of LDL cholesterol'.
- (20) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of Opti_{EFAX}TM and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (21) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Opti_{EFAX}TM and maintenance of normal blood HDL-cholesterol concentrations (Question No EFSA-Q-2012-00340) ⁽⁵⁾. The claim proposed by the applicant was worded as follows: 'Opti_{EFAX}TM helps to maintain healthy blood levels of HDL cholesterol'.
- (22) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of Opti_{EFAX}TM and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (23) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of KF2BL20, which is a combination of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin, and maintenance of normal hair (Question No EFSA-Q-2012-00381) ⁽⁶⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to maintain hair strength'.

⁽¹⁾ EFSA Journal 2012; 10(7):2807.

⁽²⁾ EFSA Journal 2012; 10(7):2805.

⁽³⁾ EFSA Journal 2012; 10(7):2819.

⁽⁴⁾ EFSA Journal 2012; 10(7):2802.

⁽⁵⁾ EFSA Journal 2012; 10(7):2803.

⁽⁶⁾ EFSA Journal 2012; 10(7):2808.

- (24) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of KF2BL20 and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (25) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of hyaluronic acid and protection of the skin against dehydration (Question No EFSA-Q-2012-00382) ⁽¹⁾. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to maintain good skin hydration'.
- (26) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of hyaluronic acid and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (27) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Opti_{EFAX}TM and maintenance of normal blood concentrations of triglycerides (Question No EFSA-Q-2012-00383) ⁽²⁾. The claim proposed by the applicant was worded as follows: 'Opti_{EFAX}TM helps to maintain healthy blood levels of triglycerides.'
- (28) On 17 July 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of Opti_{EFAX}TM and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (29) Following an application from Vivatch, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Transitech® and 'improves transit and durably regulates it' (Question No EFSA-Q-2012-00296) ⁽³⁾. The claim proposed by the applicant was worded as follows: 'Improves transit and durably regulates it'.
- (30) On 26 September 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship could not be established between the consumption of Transitech® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (31) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Femilub® and maintenance of vaginal moisture (Question No EFSA-Q-2012-00571) ⁽⁴⁾. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to reduce vaginal dryness'.
- (32) On 26 September 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of Femilub® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (33) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of a combination of lycopene, vitamin E, lutein and selenium and protection of the skin from UV-induced damage (Question No EFSA-Q-2012-00592) ⁽⁵⁾. The claim proposed by the applicant was worded, *inter alia*, as follows: 'Helps to prepare sensitive skin from the inside to improve their tolerance to the sun'.
- (34) On 27 September 2012, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of a combination of lycopene, vitamin E, lutein and selenium and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (35) Following an application from Glanbia Nutritionals plc, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of ProLibra® and 'Helps to reduce body fat while preserving lean muscle' (Question No EFSA-Q-2012-00001) ⁽⁶⁾. The claim proposed by the applicant was worded as follows: 'Helps to reduce body fat while preserving lean muscle'.
- (36) On 8 November 2012, the Commission and the Member States received the scientific opinion from the Authority,

⁽¹⁾ EFSA Journal 2012; 10(7):2806.

⁽²⁾ EFSA Journal 2012; 10(7):2804.

⁽³⁾ EFSA Journal 2012; 10(9):2887.

⁽⁴⁾ EFSA Journal 2012; 10(9):2888.

⁽⁵⁾ EFSA Journal 2012; 10(9):2890.

⁽⁶⁾ EFSA Journal 2012; 10(11):2949.

which concluded that on the basis of the data presented, a cause and effect relationship could not be established between the consumption of Prolibra® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

- (37) Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of *Eff_{EXT}*TM and 'Helps to support joint function by maintaining low levels of plasma C-reactive protein' (Question No EFSA-Q-2012-00386) ⁽¹⁾. The claim proposed by the applicant was worded, inter alia, as follows: 'Helps to support joint function by maintaining low levels of plasma C-reactive protein'.
- (38) On 27 September 2012, the Commission and the Member States received the scientific opinion from the Authority, which noted that the claim refers to a reduction of inflammation indicated by a lowered concentration of plasma C-reactive protein and concluded that on the basis of the data presented, a reduction of inflammation in the context of diseases such as osteoarthritis or rheumatoid arthritis is a therapeutic target for the treatment of a disease.
- (39) Regulation (EC) No 1924/2006 complements the general principles of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽²⁾. Article 2(1)(b) of Directive 2000/13/EC provides that the labelling shall not attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties. Accordingly, as the attribution of medicinal properties to foods is prohibited, the claim related to the effects of *Eff_{EXT}*TM should not be authorised.
- (40) The health claim related to the effects of *Eff_{EXT}*TM and 'Helps to support joint function by maintaining low levels of plasma C-reactive protein', is a health claim attributing medicinal properties to the food subject to the claim and is therefore prohibited for foods.
- (41) The health claim related to Prolibra® and 'Helps to reduce body fat while preserving lean muscle' is a health claim as those referred to in point (c) of Article 13(1) of Regulation (EC) No 1924/2006 which are subject to the transitional period laid down in Article 28(6) of that Regulation. However, as the application was not made before 19 January 2008, the

requirement provided for in point (b) of Article 28(6) of that Regulation is not fulfilled, and therefore this claim may not benefit from the transitional period provided for in that Article.

- (42) The other health claims subject to this Regulation are health claims as referred to in point (a) of Article 13(1) of Regulation (EC) No 1924/2006, which are subject to the transitional period laid down in Article 28(5) of that Regulation until the adoption of the list of permitted health claims provided that they comply with that Regulation.
- (43) The list of permitted health claims has been established by Commission Regulation (EU) No 432/2012 ⁽³⁾ and is applicable since 14 December 2012. As regards claims referred to in Article 13(5) of Regulation (EC) No 1924/2006 for which the evaluation by the Authority or consideration by the Commission has not been completed by 14 December 2012 and which by virtue of this Regulation are not included in the list of permitted health claims, it is appropriate to provide for a transitional period during which they may still be used, in order to allow both food business operators and the competent national authorities to adapt to the prohibition of such claims.
- (44) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.
- (45) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.
2. However, the health claims referred to in paragraph 1 used prior to the entry into force of this Regulation, may continue to be used for a maximum period of six months after the entry into force of this Regulation.

Article 2

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

⁽¹⁾ EFSA Journal 2012; 10(9):2889.

⁽²⁾ OJ L 109, 6.5.2000, p. 29.

⁽³⁾ OJ L 136, 25.5.2012, p. 1.

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

Done at Brussels, 30 October 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucosamine	Glucosamine contributes to the protection of joint cartilage exposed to excessive motion or loading and helps to improve the range of motion in joints	Q-2011-00907
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Glucosamine	Glucosamine contributes to the maintenance of normal joint cartilage	Q-2011-01113
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Wheat polar lipid extract	Contributes to improve skin hydration	Q-2011-01122
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Saccharomyces cerevisiae</i> var. <i>boulardii</i> CNCM I-3799	<i>Saccharomyces cerevisiae</i> var. <i>boulardii</i> CNCM I-3799 helps maintain intestinal comfort	Q-2012-00271
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, D-biotin and pumpkin seed oil (<i>Cucurbita pepo</i> L.)	Helps to increase hair number	Q-2012-00334 & Q-2012-00335
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	<i>Rhodiola rosea</i> L. extract	Helps to reduce tiredness in case of stress	Q-2012-00336
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of flaxseed oil and vitamin E	Contributes to maintain skin permeability barrier function	Q-2012-00337
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Opti _{EFAX} TM	Opti _{EFAX} TM helps to maintain healthy blood levels of LDL cholesterol	Q-2012-00339

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Opti _{EFAX} TM	Opti _{EFAX} TM helps to maintain healthy blood levels of HDL cholesterol	Q-2012-00340
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	KF2BL20	Helps to maintain hair strength	Q-2012-00381
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Hyaluronic acid	Helps to maintain good skin hydration	Q-2012-00382
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Opti _{EFAX} TM	Opti _{EFAX} TM helps to maintain healthy blood levels of triglycerides	Q-2012-00383
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Transitech®	Improves transit and durably regulates it	Q-2012-00296
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Femilub®	Helps to reduce vaginal dryness	Q-2012-00571
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of lycopene, vitamin E, lutein and selenium	Helps to prepare sensitive skin from the inside to improve their tolerance to the sun	Q-2012-00592
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Prolibra®	Helps to reduce body fat while preserving lean muscle	Q-2012-00001
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Eff _{EXT} TM	Helps to support joint function by maintaining low levels of plasma C-reactive protein	Q-2012-00386

COMMISSION REGULATION (EU) No 1067/2013

of 30 October 2013

amending Regulation (EC) No 1881/2006 as regards maximum levels of the contaminants dioxins, dioxin-like PCBs and non-dioxin-like PCBs in liver of terrestrial animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs ⁽²⁾ sets maximum levels for dioxins and dioxin-like polychlorinated biphenyls (PCBs) in a range of foodstuffs, including in the liver of certain terrestrial animals.

(2) The Scientific Panel on Contaminants in the Food Chain (The Panel) of the European Food Safety Authority (EFSA) has, on a request from the Commission, adopted on 5 July 2011 an opinion on the risk to public health related to the presence of high levels of dioxins and dioxin-like PCBs in liver from sheep and deer ⁽³⁾.

(3) The Commission requested that the opinion should indicate whether there is a potential increase in consumer health risk for subgroups of the population consuming such products (e.g. high consumers, people following specific diets, etc.). The opinion should also explore possible reasons for the findings of high levels of dioxins and PCBs in sheep and deer liver, and to provide scientific elements on the appropriateness to establish in future regulatory levels in liver on a product basis rather than on a fat basis.

(4) The Panel concluded that regular consumption of sheep liver would result on average in an approximate 20 % increase of the background exposure to dioxins and dioxin-like PCBs. On individual occasions, consumption of sheep liver could result in high intakes exceeding the tolerable weekly intake (TWI) of those contaminants. The Panel concluded that the frequent consumption of sheep liver, particularly by women of child-bearing age and children, may be a potential health concern.

(5) The Panel further concluded that soil and sediments are natural reservoirs of dioxins and PCBs. Soil-to-plant transfer of dioxins and PCBs via the root apparatus is generally of minor importance. In the past few years a number of sheep liver samples from various European countries were found to contain high concentrations of dioxins and PCBs although not being associated with specific contamination sources. For sheep, grazing activity is a primary factor for exposure. When grazing, intake of soil can occur through particles deposited on vegetables or directly when feeding on pasture herbage close to ground surface. Soil intake is remarkably variable and strongly seasonal: a median soil intake has been reported in the order of 8 % of dry matter intake. On the whole, soil intake might contribute substantially to sheep's exposure to dioxins and PCBs. Limited data are available concerning the transfer of dioxins and/or PCBs from feed to sheep liver. Depending on the polychlorinated dibenzo-p-dioxin (PCDD), polychlorinated dibenzofuran (PCDF) or PCB congeners considered, reported transfer ratios varied from 5 to 175 and were approximately four times higher for liver than for meat or kidney.

(6) EFSA concluded also that sheep liver is an important storage organ of dioxins and PCBs. The differences in metabolism could partly explain the relatively high liver storage of dioxins and related compounds in sheep compared to cattle.

(7) EFSA concluded that even if there would be a possible hepatic sequestration and the dioxins and PCBs would not be totally associated with the fat fraction of the liver, this would have no influence on the result, whether expressed on lipid or fresh weight basis, as all dioxins and PCBs are extracted during the analytical procedure irrespective of the liver compartment where they are present.

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ OJ L 364, 20.12.2006, p. 5.

⁽³⁾ EFSA Panel on Contaminants in the Food Chain (Contam); Scientific Opinion on the risk to public health related to the presence of high levels of dioxins and dioxin-like PCBs in liver from sheep and deer. *EFSA Journal* 2011; 9(7):2297. [71 pp.] doi:10.2903/j.efsa.2011.2297. Available online: www.efsa.europa.eu/efsajournal

- (8) The European Union Reference Laboratory (EURL) for dioxins and PCBs in Feed and Food was requested by the Commission to investigate how different extraction methods influence the levels of dioxins and PCBs in sheep liver with regard to reporting the analytical result on fat or wet weight basis. The EURL concluded that the variations for concentrations of dioxins and PCBs were considerably higher on fat basis compared to wet weight basis. The concentrations of dioxins and PCBs on fat basis in sheep liver were dependant on the applied extraction method or solvents and therefore on the resulting fat content. When comparing results on wet weight, the levels of dioxins and PCBs were quite comparable.
- (9) Therefore in order to ensure comparable results and an uniform enforcement approach across the Union as regards dioxins and PCBs in liver of terrestrial animals, it is appropriate to establish the maximum levels on a wet weight basis as was already established for fish liver and derived products thereof.
- (10) It is appropriate to provide that the maximum levels are not applicable to foodstuffs which are lawfully placed on the market before the date of application.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amending provisions

In the Annex to Regulation (EC) No 1881/2006, point 5.2 is replaced by the following:

‘5.2	Liver of terrestrial animals referred to in 5.1 with the exception of sheep and derived products thereof	0,30 pg/g wet weight	0,50 pg/g wet weight	3,0 ng/g wet weight
	Liver of sheep and derived products thereof	1,25 pg/g wet weight	2,00 pg/g wet weight	3,0 ng/g wet weight’

Article 2

Transitional provisions

1. This Regulation shall not apply to products which were placed on the market at a date prior to 1 January 2014 in conformity with the provisions applicable at such date.
2. The burden of proving when the products were placed on the market shall be borne by the food business operator.

Article 3

Entry into force and application

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

It shall apply from 1 January 2014.

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

Done at Brussels, 30 October 2013.

For the Commission

The President

José Manuel BARROSO

COMMISSION REGULATION (EU) No 1068/2013**of 30 October 2013****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of diphosphates (E 450), triphosphates (E 451) and polyphosphates (E 452) in wet salted fish****(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 30(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) That list may be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾.
- (3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (4) An application for authorisation of the use of diphosphates (E 450), triphosphates (E 451) and polyphosphates (E 452) in wet salted fish was submitted on 19 June 2009 and has been made available to the Member States.

- (5) Fish can be cured and preserved by adding high levels of salt to the raw material. The salting process has been developed from a single step to a multi-step process, involving a pre-salting step which allows a shorter salting time and a relatively homogenous salt concentration in the fish muscle. For this, fish is first pre-salted by injection and/or brine salting with a prepared brine with a controlled salt concentration. After that fish is dry salted (i.e. curing) to get the right salt concentration in the end product.
- (6) During this long preservation oxidation can still occur, in particular of the lipids present in the fish muscle. This will lead to a change in colour and flavour. The oxidation is accelerated by the metal ions present in the fish muscle and used salt. Because they form chemical complexes with metals ions, diphosphates (E 450), triphosphates (E 451) and polyphosphates (E 452) have been proven to be most effective to protect the salted fish against oxidation. Most of the added phosphates and the salt are removed by the soaking with water before consumption. The water content in the final wet salted product is not increased by this use of the phosphates. Salted fish of which the original colour and taste have been preserved is in particular demanded by the markets in Spain, Italy and Greece.
- (7) According to Article 3 in conjunction with Article 6(4) of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽³⁾ the use of phosphates in wet salted fish, has to be labelled in the list of ingredients. Food business operators may also mark on their products that polyphosphates have not been used.
- (8) As most of the added phosphates are removed during the soaking with water, the exposure of the consumer to the phosphates will be minimal and is for that reason not liable to have an effect on human health. It is therefore appropriate to allow the use of diphosphates (E 450), triphosphates (E 451) and polyphosphates (E 452) for the preservation of wet salted fish.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ OJ L 109, 6.5.2000, p. 29.

- (9) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. Since the authorisation of use of diphosphates (E 450), triphosphates (E 451) and polyphosphates (E 452) for the preservation of wet salted fish constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the European Food Safety Authority.
- (10) Bacalhau or Portuguese cod is produced by further drying wet salted fish. The use of polyphosphates could influence this drying process. In addition, this use could also hamper the development of the typical colour and taste of bacalhau. Salted fish that is treated with phosphates would therefore not be desired by the producers of traditional bacalhau. In order to allow the traditional bacalhau producers to adapt to the situation where fish treated with phosphates can be placed on the market a transitional period should be proposed. During this period the traditional bacalhau producers may make agreements with suppliers and become familiar with analytical methods that can be used for controlling the presence of added phosphates in the fish.
- (11) In order to further assess the impact on the availability of wet salted fish for the production of bacalhau, the Commission will, during three years, monitor the use of polyphosphates in the main salted cod producing countries.
- (12) Following the above, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,
- HAS ADOPTED THIS REGULATION:
- Article 1*
- Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.
- Article 2*
- This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 30 October 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Part E of Annex II to Regulation (EC) No 1333/2008 the following entries are inserted in the food category 09.2 'Processed fish and fishery products including molluscs and crustaceans' after the entry for E 392:

	E 450	Diphosphates	5 000	(4), (79)	only salted fish of the <i>Gadidae</i> family that have been pre-salted by injecting and/or brine salting with an at least 18 % salt solution and often followed by dry salting	Period of application: from 31 December 2013
	E 451	Triphosphates	5 000	(4), (79)	only salted fish of the <i>Gadidae</i> family that have been pre-salted by injecting and/or brine salting with an at least 18 % salt solution and often followed by dry salting	Period of application: from 31 December 2013
	E 452	Polyphosphates	5 000	(4), (79)	only salted fish of the <i>Gadidae</i> family that have been pre-salted by injecting and/or brine salting with an at least 18 % salt solution and often followed by dry salting	Period of application: from 31 December 2013
		(4): The maximum level is expressed as P ₂ O ₅				
		(79): The maximum level applies to the sum of E 450, E 451 and E 452 used individually or in a combination'				

COMMISSION REGULATION (EU) No 1069/2013

of 30 October 2013

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium phosphates (E 339) in natural casings for sausages

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

stuffing process and reducing the maximum force and breaking strain in casings.

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 30(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.

(2) That list may be amended in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾ either on the initiative of the Commission or following an application.

(3) An application for authorisation of the use of sodium phosphates (E 339) as an acidity regulator in natural casings for sausages was submitted on 26 August 2010 and has been made available to the Member States.

(4) Sodium phosphates (E 339) are included in the Union list of food additives and they are allowed to be used in certain foods, which does not include natural casings for sausages.

(5) Important efficacy-reducing mechanical characteristics of natural casings that cause problems in the sausage industry are the occurrence of burst during stuffing and reduced sliding capacity (increased stickiness) of casings over the sausage stuffing horn.

(6) Sodium phosphates (E 339), used as an acidity regulator, has been proved to be suitable to improve the sliding properties of natural casings facilitating the sausage

(7) The maximum tolerable daily intake (MTDI) of phosphates established by the Scientific Committee for Food ⁽³⁾ is 70 mg/kg body weight. The maximum level proposed by the applicant is 12 600 mg/kg of casings leading to a maximum carry-over of phosphates from casings in the final sausage of 250 mg/kg. The highest contribution of phosphates via treated natural casings will be 2,1 % of the MTDI. It is therefore appropriate to allow the use of sodium phosphates as an acidity regulator to improve the mechanical properties of casings for sausages.

(8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. Since the authorisation of use of sodium phosphates (E 339) for the improvement of the mechanical properties of natural casings for sausages constitutes an update of that list which is not liable to have an effect on human health for the aforesaid reasons, it is not necessary to seek the opinion of the European Food Safety Authority.

(9) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Reports of the Scientific Committee for Food, Twenty-fifth series (page 13), 1991, available at http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_25.pdf

Article 2

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

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

Done at Brussels, 30 October 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Part E of Annex II to Regulation (EC) No 1333/2008, the following entry is inserted in the food category 08.2.3 'Casings and coatings and decoration for meat' after the entry for E 338-452:

	E 339	Sodium phosphates	12 600	(4) (80)	only in natural casings for sausages
		(4): The maximum level is expressed as P ₂ O ₅			
		(80): Carry-over in the final product shall not exceed 250 mg/kg'			

COMMISSION IMPLEMENTING REGULATION (EU) No 1070/2013**of 30 October 2013****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 Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral 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 XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 30 October 2013.

*For the Commission,
On behalf of the President,*

Jerzy PLEWA
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, 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	AL	41,5
	MA	43,1
	MK	43,1
	TR	75,3
	ZZ	50,8
0707 00 05	EG	207,6
	MK	69,6
	TR	139,0
	ZZ	138,7
0709 93 10	TR	112,3
	ZZ	112,3
0805 50 10	AR	12,9
	CL	81,7
	TR	76,3
	ZA	55,9
	ZZ	56,7
0806 10 10	BR	220,8
	TR	170,3
	ZZ	195,6
0808 10 80	CL	216,7
	NZ	142,8
	US	154,3
	ZA	141,7
	ZZ	163,9
0808 30 90	CN	76,9
	TR	120,5
	ZZ	98,7

⁽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'.

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 29 October 2013

approving restrictions of the authorisation of one biocidal product containing bromadiolone notified by Germany in accordance with Directive 98/8/EC of the European Parliament and of the Council

*(notified under document C(2013) 7034)***(Only the German text is authentic)**

(2013/630/EU)

THE EUROPEAN COMMISSION,

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

Having regard 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⁾, and in particular Article 4(4) thereof,

Whereas:

(1) Annex I to Directive 98/8/EC contains the list of active substances approved at Union level for inclusion in biocidal products. Commission Directive 2009/92/EC ⁽²⁾ added the active substance bromadiolone for use in products belonging to product-type 14, Rodenticides, as defined in Annex V to Directive 98/8/EC.

(2) Bromadiolone is an anticoagulant rodenticide known to pose risks of accidental incidents with children, as well as risks for non-target animals and the environment. It has been identified as potentially persistent, liable to bioaccumulate and toxic ('PBT'), or very persistent and very liable to bioaccumulate ('vPvB').

(3) For reasons of public health and hygiene, it was nevertheless found to be justified to include bromadiolone and other anticoagulant rodenticides in Annex I to Directive 98/8/EC, thus allowing Member States to authorise bromadiolone-based products. However, Directive 2009/92/EC obliges Member States to ensure, when granting authorisation of products containing bromadiolone, that primary as well as secondary exposure of

humans, non-target animals and the environment is minimised, by considering and applying all appropriate and available risk mitigation measures. The risk mitigation measures mentioned in Directive 2009/92/EC therefore include, amongst others, restriction to professional use only.

(4) The company Lipha Tech S.A.S. ('the applicant') has, in accordance with Article 8 of Directive 98/8/EC, submitted an application to the Netherlands for authorisation of one rodenticide containing bromadiolone ('the product'). The product's name and reference numbers in the Register for Biocidal Products ('R4BP') are indicated in the Annex to this Decision.

(5) The Netherlands granted the authorisation on 2 November 2012. The product was authorised with restrictions to ensure that the conditions of Article 5 of Directive 98/8/EC were met in the Netherlands. Those restrictions did not include restriction to trained or licensed professional users.

(6) On 20 December 2012, the applicant submitted a complete application to Germany for mutual recognition of the first authorisation in respect of the product.

(7) On 10 April 2013, Germany notified the Commission, the other Member States and the applicant of its proposal to restrict the first authorisation in accordance with Article 4(4) of Directive 98/8/EC. Germany proposed to impose a restriction on the product to use by trained or licensed professionals.

(8) The Commission invited the other Member States and the applicant to submit comments to the notification in writing within 90 days in accordance with Article 27(1) of Directive 98/8/EC. No comments were submitted within that deadline. The notification was also discussed between the Commission and Member States' Competent Authorities for biocidal products in the meeting of the Product Authorisation and Mutual Recognition Facilitation Group of 14 May 2013.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ Commission Directive 2009/92/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include bromadiolone as an active substance in Annex I thereto (OJ L 201, 1.8.2009, p. 43).

- (9) In accordance with Directive 2009/92/EC, authorisations of biocidal products containing bromadiolone are to be subject to all appropriate and available risk mitigation measures, including the restriction to professional use only. The scientific evaluation leading to the adoption of Directive 2009/92/EC concluded that only professional users could be expected to follow the instructions minimising the risk of secondary poisoning of non-target animals, and to use products in a way that prevents the selection and spreading of resistance. A restriction to professional users should therefore in principle be considered to be an appropriate risk mitigation measure, in particular in Member States where resistance to bromadiolone occurs.
- (10) In the absence of any indication to the contrary, restriction to professional users is therefore an appropriate and available risk mitigation measure for the authorisation of products containing bromadiolone in Germany. This conclusion is reinforced by the arguments put forward by Germany that resistance against bromadiolone in rats has been found and is thought to be developing in the country. Furthermore, Germany has a well-functioning infrastructure of trained pest control operators and licensed professionals, such as farmers, gardeners and foresters who received professional training, which means that the proposed restriction does not hinder infection prevention.

- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Germany may restrict the authorisation granted in accordance with Article 4 of Directive 98/8/EC for the product mentioned in the Annex to this Decision to use by trained or licensed professionals.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 29 October 2013.

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

Product for which Germany may restrict the authorisation granted in accordance with Article 4 of Directive 98/8/EC to use by trained or licensed professionals:

Product name in the Netherlands	Dutch application reference number in the Register for Biocidal Products	Product name in Germany	German application reference number in the Register for Biocidal Products
Maki Pat'	2011/4329/10506/NL/AA/20379	Maki Pat'	2011/4329/10506/DE/MA/20799

COMMISSION DECISION

of 29 October 2013

on the compliance of 2014 unit rates for charging zones under Article 17 of Implementing Regulation (EU) No 391/2013

(notified under document C(2013) 7095)

(2013/631/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the Single European Sky (the service provision Regulation) ⁽¹⁾ and in particular Article 15 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 391/2013 ⁽²⁾ lays down a common charging scheme for air navigation services. The common charging scheme is an integral element in reaching the objectives of the performance scheme as established under Article 11 of Regulation (EC) No 549/2004 of the European Parliament and of the Council ⁽³⁾ and Commission Implementing Regulation (EU) No 390/2013 ⁽⁴⁾.
- (2) Commission Decision 2011/121/EU ⁽⁵⁾ set European Union-wide performance targets including a cost-efficiency target for the provision of air navigation services for the years 2012 to 2014. By letters of 19 July 2012 and 17 December 2012 the Commission informed Member States that their revised performance plans and targets are consistent with, and adequately contributing to, the adopted European Union-wide performance targets. Cost-efficiency targets are expressed in terms of determined unit rates.

- (3) Article 17(1)(c) of Implementing Regulation (EU) No 391/2013 provides that the Commission shall assess the 2014 unit rates for charging zones submitted by the Member States to the Commission by 1 June 2013 following the requirements of Article 9(1) and 9(2) of that Regulation. This assessment shall check the compliance of the 2014 unit rates with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
- (4) The Commission has carried out its assessment of the 2014 unit rates for charging zones with the support of the Performance Review Body (PRB) and Eurocontrol's Central Route Charges Office and using the data and additional information provided by the Member States by June 2013. The assessment also took into account the explanations given and corrections made before the consultation meeting held on 26 June 2013 in application of Article 9(1) of Implementing Regulation (EU) No 391/2013 as well as subsequent correspondence between the Commission and Denmark, Estonia, Ireland, Spain, France, Italy, Hungary, Malta, the Netherlands, Romania, Sweden and the United Kingdom.
- (5) Denmark, France, Italy, the Netherlands and Romania proposed to partially or fully offset the adjustments foreseen under Implementing Regulation (EU) No 391/2013 with the effect of lowering or maintaining a certain level of the unit rate, which is in the interest of airspace users. Therefore, these amounts should not be recovered in subsequent years.
- (6) The Commission notes that Spain intends to apply a transitional provision in accordance with Article 2 of Commission Regulation (EU) No 1191/2010 ⁽⁶⁾. The Commission has verified the information provided by Spain in this regard and agrees that Spain fulfils the conditions of Article 2 of Regulation (EU) No 1191/2010 and may decide to exempt from Article 11a(3) of Commission Regulation (EC) No 1794/2006 ⁽⁷⁾ the determined costs of providers of air navigation services. Thus, the traffic risk sharing

⁽¹⁾ OJ L 96, 31.3.2004, p. 10.

⁽²⁾ Commission Implementing Regulation (EU) No 391/2013 of 3 May 2013 laying down a common charging scheme for air navigation services (OJ L 128, 9.5.2013, p. 31).

⁽³⁾ Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the Single European Sky (the framework Regulation) (OJ L 96, 31.3.2004, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 390/2013 of 3 May 2013 laying down a performance scheme for air navigation services and network functions (OJ L 128, 9.5.2013, p. 1).

⁽⁵⁾ Commission Decision 2011/121/EU of 21 February 2011 setting the European Union-wide performance targets and alert thresholds for the provision of air navigation services for the years 2012 to 2014 (OJ L 48, 23.2.2011, p. 16).

⁽⁶⁾ Commission Regulation (EU) No 1191/2010 of 16 December 2010 amending Regulation (EC) No 1794/2006 laying down a common charging scheme for air navigation services (OJ L 333, 17.12.2010, p. 6).

⁽⁷⁾ Commission Regulation (EC) No 1794/2006 of 6 December 2006 laying down a common charging scheme for air navigation services (OJ L 341, 7.12.2006, p. 3).

mechanism with its 30/70 sharing between air navigation service providers and airspace users of the gain or loss resulting from a difference between actual service units and forecasted service units should apply already as of 0 % difference instead of 2 % difference. In line with Article 2 of Regulation (EU) No 1191/2010 and the reduction of the unit rate decided by Spain for the year 2012, this exemption is limited to the traffic risk sharing in respect to the revenues of that year. Spain intends to spread the resulting carry-over over the next years, starting from 2015.

- (7) Article 17(1)(d) of Implementing Regulation (EU) No 391/2013 provides that the Commission shall notify the Member States concerned where the unit rates comply with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
- (8) The notification that unit rates for charging zones are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 should be without prejudice to Article 16 of Regulation (EC) No 550/2004,

HAS ADOPTED THIS DECISION:

Article 1

The 2014 unit rates for charging zones in the Annex to this Decision are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.

Article 2

The notification that unit rates for charging zones are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 is without prejudice to Article 16 of Regulation (EC) No 550/2004.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 29 October 2013.

For the Commission

Siim KALLAS

Vice-President

ANNEX

Charging zone	2014 en route unit rate in national currency ⁽¹⁾ (ISO Code)
Belgium and Luxembourg	72,04 EUR
Bulgaria	73,50 BGN
Czech Republic	1 198,16 CZK
Denmark	537,56 DKK
Germany	77,32 EUR
Estonia	23,97 EUR
Ireland	30,62 EUR
Greece	34,53 EUR
Spain Continental	71,69 EUR
Spain Canary Islands	58,36 EUR
France	65,77 EUR
Italy	78,83 EUR
Cyprus	38,41 EUR
Latvia	19,99 LVL
Lithuania	162,08 LTL
Hungary	13 190,76 HUF
Malta	27,61 EUR
Netherlands	66,47 EUR
Austria	73,39 EUR
Poland	148,89 PLN
Portugal — Lisbon	38,74 EUR
Romania	168,83 RON
Slovenia	67,46 EUR
Slovak Republic	60,04 EUR
Finland	52,06 EUR
Sweden	638,85 SEK
United Kingdom	70,46 GBP

⁽¹⁾ These unit rates do not include the administrative unit rate referred to in Article 18 of Implementing Regulation (EU) No 391/2013 and applying to those States parties to Eurocontrol's Multilateral Agreement relating to route charges.

COMMISSION IMPLEMENTING DECISION

of 30 October 2013

confirming the average specific emissions of CO₂ and specific emissions targets for manufacturers of passenger cars for the calendar year 2012 pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council

(Text with EEA relevance)

(2013/632/EU)

THE EUROPEAN COMMISSION,

information in accordance with Article 3(1) of Commission Regulation (EU) No 1014/2010 ⁽²⁾.

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

Having regard to Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO₂ emissions from light-duty vehicles ⁽¹⁾, and in particular the second subparagraph of Article 8(5) and Article 10(1) thereof,

Whereas:

(1) The Commission is required, pursuant to Article 8(5) of Regulation (EC) No 443/2009, to confirm each year the average specific emissions of CO₂ and the specific emissions target for each manufacturer of passenger cars in the Union as well as for each pool of manufacturers formed in accordance with Article 7(1) of that Regulation. On the basis of that confirmation, the Commission is to determine whether manufacturers and pools have complied with the requirements of Article 4 of that Regulation.

(2) Pursuant to Article 4 of Regulation (EC) No 443/2009, the targets are binding on manufacturers and pools with effect from 2012. The average specific emissions of manufacturers for 2012 are calculated in accordance with the second paragraph of that Article and take into account 65 % of the manufacturer's new cars registered in that year.

(3) The detailed data to be used for the calculation of the average specific emissions and the specific emissions targets is set out in point 1 of Part A and in Part C of Annex II to Regulation (EC) No 443/2009 and is based on Member States' registrations of new passenger cars during the preceding calendar year. The data is taken from the certificates of conformity issued by the manufacturers or from documents providing equivalent

(4) All Member States submitted the data for 2012 to the Commission by the deadline of 28 February 2013 in accordance with Article 8(2) of Regulation (EC) No 443/2009. Where, as a result of the verification of the data by the Commission, it was evident that certain data were missing or manifestly incorrect, the Commission contacted the Member States concerned and, subject to the agreement of those Member States, adjusted or completed the data accordingly. Where no agreement could be reached with a Member State, the provisional data of that Member State was not adjusted.

(5) On 30 April 2013, the Commission published the provisional data and notified 85 manufacturers of the provisional calculations of their average specific emissions of CO₂ in 2012 and their specific emissions targets in accordance with Article 8(4) of Regulation (EC) No 443/2009. Manufacturers were asked to verify the data and to notify the Commission of any errors within three months of receipt of the notification in accordance with the first subparagraph of Article 8(5) of that Regulation and Article 9(3) of Regulation (EU) No 1014/2010. Eight manufacturers accepted the preliminary data without corrections whilst 40 manufacturers submitted notifications of errors within the given deadline.

(6) For the remaining 37 manufacturers that did not notify any errors in the datasets or respond otherwise, the provisional data and provisional calculations of the average specific emissions and the specific emissions targets should be confirmed without adjustments.

(7) The Commission has verified the corrections notified by the manufacturers and the respective justifications as expressed through the error codes specified in Article 9(3) of Regulation (EU) No 1014/2010 and the dataset has been adjusted as appropriate.

⁽¹⁾ OJ L 140, 5.6.2009, p. 1.

⁽²⁾ Commission Regulation (EU) No 1014/2010 of 10 November 2010 on monitoring and reporting of data on the registration of new passenger cars pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council (OJ L 293, 11.11.2010, p. 15).

- (8) In the case of records that have been identified by manufacturers with the error code B as set out in Article 9(3) of Regulation (EU) No 1014/2010, it is necessary to take into account the fact that manufacturers cannot verify or correct those records appropriately due to missing or incorrect identification parameters. Accordingly, an error margin should be applied to the CO₂ emission and mass values in those records.
- (9) The error margin should be calculated as the difference between the distances to the specific emissions target expressed as the average emissions subtracted from the specific emissions targets calculated including and excluding those registrations that cannot be verified by the manufacturers. Regardless of whether that difference is positive or negative, the error margin should always improve the distance to the target of the manufacturer.
- (10) In accordance with Article 10(2) of Regulation (EC) No 443/2009, a manufacturer should be considered as compliant with its specific emission target referred to in Article 4 of that Regulation where the average emissions indicated in this Decision are lower than the specific emissions target, expressed as a negative distance to target. Where the average emissions exceed the specific emissions target, an excess emission premium should be imposed in accordance with Article 9 of Regulation (EC) No 443/2009, unless the manufacturer concerned benefits from an exemption from that target or is a member of a pool in accordance with Article 7 of that Regulation and the pool complies with its specific emissions target.
- (11) The average specific emissions of CO₂ from new passenger cars registered in 2012, the specific emissions targets and the difference between those two values should be confirmed accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following values specified in the Annex are confirmed for each manufacturer of passenger cars and for each pool of manufacturers in respect of the 2012 calendar year:

- (a) the specific emissions target;
- (b) the average specific emissions of CO₂, where appropriate adjusted by the relevant error margin;
- (c) the difference between the values referred to in points (a) and (b);
- (d) the average specific emissions of CO₂ for all new passenger cars in the Union;
- (e) the average mass for all new passenger cars in the Union.

Article 2

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

Done at Brussels, 30 October 2013.

For the Commission
The President

José Manuel BARROSO

ANNEX

Table 1

Values relating to the performance of manufacturers confirmed in accordance with Article 10 of Regulation (EC) No 443/2009

A	B	C	D	E	F	G	H	I
Manufacturer Name	Pools and Derogations	Number of registrations	Average CO ₂ (65 %) corrected	Specific emissions target	Distance to target	Distance to target adjusted	Average mass	Average CO ₂ (100 %)
ALPINA BURKARD BOVENSIEPEN GMBH E CO., KG		459	156,768	152,125	4,643	4,643	1 856,13	183,037
ARTEGA AUTOMOBIL GMBH E CO., KG		4	223,000	126,024	96,976	96,976	1 285,00	223,000
ASTON MARTIN LAGONDA LTD	D	1 549	296,355	320,000	– 23,645	– 23,645	1 774,48	321,944
AUDI AG	P12	657 068	122,411	139,473	– 17,062	– 17,110	1 579,29	137,786
AUDI HUNGARIA MOTOR KFT	P12	11 241	137,324	133,613	3,711	3,573	1 451,07	149,057
AUTOMOBILES CITROEN		654 993	108,718	129,703	– 20,985	– 20,985	1 365,51	122,566
AUTOMOBILES PEUGEOT		773 864	107,648	130,413	– 22,765	– 22,765	1 381,03	121,489
AVTOVAZ JSC	P8	2 298	207,903	125,748	82,155	82,155	1 278,96	213,899
BENTLEY MOTORS LTD	P12	1 992	310,230	181,440	128,790	128,790	2 497,60	338,040
BAYERISCHE MOTOREN WERKE AG	P1	762 027	123,643	138,696	– 15,053	– 15,111	1 562,28	137,515
BMW M GMBH	P1	6 375	231,079	151,103	79,976	78,034	1 833,77	247,941
BUGATTI AUTOMOBILES S.A.S	P12	2	539,000	156,689	382,311	382,311	1 956,00	539,000
CATERHAM CARS LIMITED	D	139	174,178	210,000	– 35,822	– 35,822	704,32	188,921
CECOMP S.P.A.		1 001	0,000	123,282	– 123,282	– 123,282	1 225,00	0,000
CHEVROLET ITALIA SPA	P5	4 948	110,000	114,681	– 4,681	– 4,681	1 036,80	110,284
CHRYSLER GROUP LLC	P3	57 034	177,442	159,650	17,792	17,295	2 020,79	192,882
CNG-TECHNIK GMBH	P4	75	113,938	118,091	– 4,153	– 4,153	1 111,40	113,960

A	B	C	D	E	F	G	H	I
Manufacturer Name	Pools and Derogations	Number of registrations	Average CO ₂ (65 %) corrected	Specific emissions target	Distance to target	Distance to target adjusted	Average mass	Average CO ₂ (100 %)
AUTOMOBILE DACIA SA	P8	232 256	125,132	126,664	– 1,532	– 1,534	1 299,01	136,899
DAIHATSU MOTOR CO LTD	P11	3 397	131,952	120,887	11,065	11,065	1 172,58	148,590
DAIMLER AG	P2	631 475	123,873	139,576	– 15,703	– 15,716	1 581,53	142,842
DONGFENG MOTOR CORPORATION		2	184,000	118,758	65,242	65,242	1 126,00	187,000
DR MOTOR COMPANY SRL		645	126,489	122,520	3,969	3,969	1 208,33	141,574
FERRARI S.P.A	D	2 330	298,539	303,000	– 4,461	– 4,461	1 733,67	316,739
FIAT GROUP AUTOMOBILES S.P.A	P3	686 449	109,841	118,886	– 9,045	– 9,171	1 128,80	117,233
FISKER AUTOMOTIVE INC		166	53,000	181,778	– 128,778	– 128,778	2 505,00	53,000
FORD-WERKE GMBH	P4	917 725	116,480	127,832	– 11,352	– 11,359	1 324,57	128,685
FUJI HEAVY INDUSTRIES LTD	ND	29 381	150,266	164,616	– 14,350	– 14,350	1 561,77	160,599
GENERAL MOTORS COMPANY	P5	2 673	130,061	154,444	– 24,383	– 24,383	1 906,87	253,869
GM ITALIA SRL	P5	2	119,000	123,968	– 4,968	– 4,968	1 240,00	119,000
GM KOREA COMPANY	P5	161 153	124,248	131,444	– 7,196	– 7,196	1 403,59	141,050
GREAT WALL MOTOR COMPANY LIMITED	D	309	168,000	195,000	– 27,000	– 27,000	1 184,23	169,049
HONDA AUTOMOBILE CHINA CO., LTD	P6	17 668	123,408	119,912	3,496	3,496	1 151,26	124,855
HONDA MOTOR CO., LTD	P6	71 717	121,571	130,995	– 9,424	– 9,424	1 393,77	138,965
HONDA TURKIYE AS	P6	2 207	154,787	128,725	26,062	26,062	1 344,10	157,874
HONDA OF THE UK MANUFACTURING LTD	P6	40 779	139,093	136,324	2,769	2,769	1 510,38	156,169
HYUNDAI MOTOR COMPANY		416 987	118,808	128,266	– 9,458	– 9,458	1 334,05	132,203
IVECO S.P.A	P3	6	143,333	224,310	– 80,977	– 80,977	3 435,67	146,667
JAGUAR	ND; P10	22 621	150,844	178,025	– 27,181	– 27,409	1 910,74	168,970

A	B	C	D	E	F	G	H	I
Manufacturer Name	Pools and Derogations	Number of registrations	Average CO ₂ (65 %) corrected	Specific emissions target	Distance to target	Distance to target adjusted	Average mass	Average CO ₂ (100 %)
JIANGLING MOTOR HOLDING CO., LTD		39	144,480	130,348	14,132	14,132	1 379,62	147,897
KIA MOTORS CORPORATION		329 474	114,489	127,175	- 12,686	- 12,686	1 310,18	129,464
KTM-SPORTMOTORCYCLE AG	D	18	180,000	200,000	- 20,000	- 20,000	875,00	183,000
AUTOMOBILI LAMBORGHINI S.P.A	P12	413	343,683	144,315	199,368	199,021	1 685,23	364,295
LAND ROVER	ND; P10	98 731	167,445	178,025	- 10,580	- 10,583	2 123,81	190,922
LOTUS CARS LIMITED	D	335	163,447	280,000	- 116,553	- 116,553	1 181,82	185,857
MAGYAR SUZUKI CORPORATION LTD	P9	84 045	118,669	120,317	- 1,648	- 1,654	1 160,12	128,118
MAHINDRA & MAHINDRA LTD	D	64	179,000	205,000	- 26,000	- 26,000	1 915,08	182,234
MARUTI SUZUKI INDIA LTD	P9	21 574	101,217	109,891	- 8,674	- 8,674	931,97	102,884
MASERATI S.P.A	P3	883	343,492	158,286	185,206	184,578	1 990,95	351,072
MAZDA MOTOR CORPORATION		113 565	128,793	129,494	- 0,701	- 0,701	1 360,93	141,779
MCLAREN AUTOMOTIVE LIMITED	D	335	279,000	285,000	- 6,000	- 6,000	1 511,50	279,475
MERCEDES-AMG GMBH	P2	2 939	177,053	151,465	25,588	25,305	1 841,70	222,641
MG MOTOR UK LIMITED	D	755	176,147	184,000	- 7,853	- 7,853	1 585,69	178,914
MIA ELECTRIC S.A.S		494	0,000	107,916	- 107,916	- 107,916	888,76	0,000
MICRO-VETT S.P.A		5	0,000	130,091	- 130,091	- 130,091	1 374,00	0,000
MITSUBISHI MOTORS CORPORATION MMC	P7	48 688	126,281	140,924	- 14,643	- 15,397	1 611,04	151,332
MITSUBISHI MOTORS EUROPE BV MME	P7	18 604	117,601	118,511	- 0,910	- 0,981	1 120,59	126,014
MITSUBISHI MOTORS THAILAND CO LTD MMTH	P7	15	97,778	123,575	- 25,797	- 26,331	1 231,40	125,667
MORGAN MOTOR CO LTD	D	398	156,050	180,000	- 23,950	- 23,950	1 120,11	184,078
NISSAN INTERNATIONAL SA		423 818	122,253	131,177	- 8,924	- 8,924	1 397,75	137,341

A	B	C	D	E	F	G	H	I
Manufacturer Name	Pools and Derogations	Number of registrations	Average CO ₂ (65 %) corrected	Specific emissions target	Distance to target	Distance to target adjusted	Average mass	Average CO ₂ (100 %)
OMCI SRL		21	148,000	116,656	31,344	31,344	1 080,00	156,667
ADAM OPEL AG	P5	814 229	119,708	133,821	– 14,113	– 14,114	1 455,62	133,002
PERODUA MANUFACTURING SDN BHD		372	136,934	113,647	23,287	23,287	1 014,16	140,785
DR ING HCF PORSCHE AG	P12	42 299	187,954	152,535	35,419	35,419	1 865,10	205,379
PERUSAHAAN OTOMOBIL NASIONAL SDN BHD	D	206	146,511	185,000	– 38,489	– 38,489	1 311,58	154,942
QUATTRO GMBH	P12	3 904	219,136	147,404	71,732	70,977	1 752,84	243,966
RADICAL MOTORSPORT LTD		6	229,000	106,145	122,855	122,855	850,00	229,000
RENAULT S.A.S	P8	800 674	105,396	126,744	– 21,348	– 21,353	1 300,76	120,796
ROLLS-ROYCE MOTOR CARS LTD	P1	417	317,376	181,976	135,400	135,377	2 509,34	329,930
SAAB AUTOMOBILE AB		1 297	151,696	144,382	7,314	7,314	1 686,71	170,266
SEAT SA	P12	252 173	114,757	127,124	– 12,367	– 12,521	1 309,07	127,191
SECMA S.A.S		40	131,000	97,370	33,630	33,630	658,00	131,000
SHIJIAZHANG SHUANGHUAN AUTOMOBILE COMPANY		10	269,667	154,130	115,537	115,537	1 900,00	269,800
SKODA AUTO AS	P12	460 603	120,028	126,655	– 6,627	– 7,026	1 298,81	132,247
SPYKER AUTOMOBIELEN BV	D	2	340,000	340,000	0,000	0,000	1 730,00	340,000
SSANGYONG MOTOR COMPANY	D	4 967	167,641	180,000	– 12,359	– 12,359	1 812,62	186,532
SUZUKI MOTOR CORPORATION	P9	46 255	131,108	124,115	6,993	6,891	1 243,22	148,213
TATA MOTORS LIMITED	ND; P10	592	134,367	178,025	– 43,658	– 43,658	1 336,03	141,978
TESLA MOTORS LTD		159	0,000	128,309	– 128,309	– 128,309	1 335,00	0,000
THINK		52	0,000	118,360	– 118,360	– 118,360	1 117,29	0,000

A	B	C	D	E	F	G	H	I
Manufacturer Name	Pools and Derogations	Number of registrations	Average CO ₂ (65 %) corrected	Specific emissions target	Distance to target	Distance to target adjusted	Average mass	Average CO ₂ (100 %)
TOYOTA MOTOR EUROPE NV SA	P11	515 028	103,613	127,912	– 24,299	– 24,371	1 326,30	121,862
VEHICULES ELECTRIQUES PININFARINA-BOLLORE S.A.S.		542	0,000	123,282	– 123,282	– 123,282	1 225,00	0,000
VOLKSWAGEN AG	P12	1 535 755	119,343	131,203	– 11,860	– 11,952	1 398,32	132,965
VOLVO CAR CORPORATION		204 539	121,944	144,736	– 22,792	– 22,792	1 694,44	142,116
WIESMANN GMBH	D	53	284,294	274,000	10,294	10,294	1 490,38	289,566
ZHEJIANG ZOTYE AUTOMOBILE MANUFACTURING CO., LTD		2	0,000	128,172	– 128,172	– 128,172	1 332,00	75,000

Table 2

Values relating to the performance of pools confirmed in accordance with Article 10 of Regulation (EC) No 443/2009

A	B	C	D	E	F	G	H	I
Pool Name	Pool	Number of registrations	Average CO ₂ (65 %) corrected	Specific emissions target	Distance to target	Distance to target adjusted	Average mass	Average CO ₂ (100 %)
BMW GROUP	P1	768 819	123,824	138,822	– 14,998	– 15,052	1 565,05	138,535
DAIMLER AG	P2	634 414	123,949	139,630	– 15,681	– 15,694	1 582,73	143,212
FIAT GROUP AUTOMOBILES SPA	P3	744 372	110,597	122,056	– 11,459	– 11,468	1 198,18	123,307
FORD-WERKE GMBH	P4	917 800	116,479	127,832	– 11,353	– 11,361	1 324,55	128,684
GENERAL MOTORS	P5	983 005	119,853	133,391	– 13,538	– 13,539	1 446,21	134,536
HONDA MOTOR EUROPE LTD	P6	132 371	125,014	131,120	– 6,106	– 6,106	1 396,5	142,697
MITSUBISHI MOTORS	P7	67 307	122,126	134,725	– 12,599	– 13,121	1 475,39	144,328
POOL RENAULT	P8	1 035 228	109,427	126,724	– 17,297	– 17,301	1 300,32	124,615
SUZUKI	P9	151 874	115,511	119,993	– 4,482	– 4,498	1 153,02	130,654
TATA MOTORS LTD, JAGUAR CARS LTD, LAND ROVER	P10	121 944	162,825	178,025	– 15,200	– 15,307	2 080,46	186,612
TOYOTA-DAIHATSU GROUP	P11	518 425	103,694	127,865	– 24,171	– 24,239	1 325,29	122,037
VW GROUP PC	P12	2 965 450	120,108	132,353	– 12,245	– 12,508	1 423,48	134,841

Explanatory notes to Tables 1 and 2*Column A:*

Table 1: 'Manufacturer name' means the name of the manufacturer as notified to the Commission by the manufacturer concerned or, where no such notification has taken place, the name registered by the registration authority of the Member State.

Table 2: 'Pool name' means the name of the pool declared by the pool manager.

Column B:

'D' means that a derogation relating to a small volume manufacturer has been granted in accordance with Article 11(3) of Regulation (EC) No 443/2009 with effect from 2012;

'ND' means that a derogation relating to a niche manufacturer has been granted in accordance with Article 11(4) of Regulation (EC) No 443/2009 with effect from 2012;

'P' means that the manufacturer is a member of a pool (listed in Table 2) formed in accordance with Article 7 of Regulation (EC) No 443/2009 and the pooling agreement is valid for calendar year 2012.

Column C:

'Number of registrations' means the total number of new cars registered by Member States in a calendar year, not counting those registrations that relate to records where the values for mass and/or CO₂ are missing and those records which the manufacturer does not recognise (identified in the error notification with error code C as set out in Article 9(3) of Regulation (EU) No 1014/2010). The number of registrations reported by Member States may otherwise not be changed.

Column D:

'Average CO₂ (65 %) corrected' means the average specific emissions of CO₂ that have been calculated on the basis of the 65 % lowest emitting vehicles in the manufacturer's fleet in accordance with the first indent of the second subparagraph of Article 4 of Regulation (EC) No 443/2009 and point 4 of Commission Communication COM(2010) 657 final. Where appropriate, the average specific emissions have been adjusted to take into account the corrections notified to the Commission by the manufacturer concerned. The records used for the calculation include those that contain a valid value for mass and CO₂ emissions.

Column E:

'Specific emissions target' means the emissions target calculated on the basis of the average mass of all vehicles attributed to a manufacturer applying the formula set out in Annex I to Regulation (EC) No 443/2009.

Column F:

'Distance to target' means the difference between the average specific emissions specified in column D and the specific emissions target in column E. Where the value in column F is positive the average specific emissions exceed the specific emissions target.

Column G:

'Distance to target adjusted' means that where the values in this column are different from those in column F, the values in that column have been adjusted to take into account an error margin. The error margin only applies if the manufacturer has notified the Commission of records with the error code B as set out in Article 9(3) of Regulation (EU) No 1014/2010. The error margin is calculated in accordance with the following formula:

$$\text{Error} = \text{absolute value of } [(AC1 - TG1) - (AC2 - TG2)]$$

AC1 = the average specific emissions of CO₂ including the unidentifiable vehicles (as set out in column D);

TG1 = the specific emissions target including the unidentifiable vehicles (as set out in column E);

AC2 = the average specific emissions of CO₂ excluding the unidentifiable vehicles;

TG2 = the specific emissions target excluding the unidentifiable vehicles.

Column I:

'Average CO₂ (100 %)' means the average specific emissions of CO₂ that have been calculated on the basis of 100 % of the vehicles attributed to the manufacturer. Where appropriate, the average specific emissions have been adjusted to take into account the corrections notified to the Commission by the manufacturer concerned. The records used for the calculation includes those that contain a valid value for mass and CO₂ emissions but do not take into account the super-credits referred to in Article 5 of Regulation (EC) No 443/2009.

DECISIONS

2013/630/EU:

★ Commission Implementing Decision of 29 October 2013 approving restrictions of the authorisation of one biocidal product containing bromadiolone notified by Germany in accordance with Directive 98/8/EC of the European Parliament and of the Council (notified under document C(2013) 7034)	65
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2013/631/EU:

★ Commission Decision of 29 October 2013 on the compliance of 2014 unit rates for charging zones under Article 17 of Implementing Regulation (EU) No 391/2013 (notified under document C(2013) 7095)	68
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2013/632/EU:

★ Commission Implementing Decision of 30 October 2013 confirming the average specific emissions of CO ₂ and specific emissions targets for manufacturers of passenger cars for the calendar year 2012 pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council ⁽¹⁾	71
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⁽¹⁾ Text with EEA relevance

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