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I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COUNCIL REGULATION (EC) No 1104/2008

of 24 October 2008

on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 66 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Whereas:

- (1) The Schengen Information System (SIS) set up pursuant to the provisions of Title IV of the Convention of 19 June 1990 implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders (2) (the Schengen Convention), and the further development, thereof, SIS 1+, constitute essential tools for the application of the provisions of the Schengen acquis as integrated into the framework of the European Union.
- The development of the second generation Schengen (2)Information System (SIS II) was entrusted to the Commission pursuant to Council Regulation (EC) No 2424/2001 (3) and Decision 2001/886/JHA (4). Those instruments expire on 31 December 2008. This Regulation should therefore supplement them until a date to be fixed by the Council acting in accordance with Regulation (EC) No 1987/2006 of the European Parliament and of the Council of 20 December 2006 on the establishment, operation and use of the second generation Schengen Information System (SIS II) (5).

As regards SIS 1+, the Schengen Convention provides for a technical support function (C.SIS). As regards SIS II, (EC) No 1987/2006 and Decision Regulation 2007/533/JHA provide for a Central SIS II composed of a technical support function and a uniform national interface (NI-SIS). The technical support function of Central SIS II should be located in Strasbourg (France) and a backup in St Johann im Pongau (Austria).

- SIS II was established by Regulation (EC) No 1987/2006 and by Council Decision 2007/533/JHA of 12 June 2007 on the establishment, operation and use of the second generation Schengen Information System (SIS II) (6). This Regulation should be without prejudice to the provisions of those acts.
- Certain tests of SIS II are provided for in Council (4)Regulation (EC) No 189/2008 (7) and in Decision 2008/173/EC (8).
- The development of SIS II should be continued and should be finalised in the framework of the SIS II global schedule endorsed by the Council on 6 June 2008.

A comprehensive test of SIS II should be conducted in

full cooperation between the Member States and the

Commission, in accordance with the provisions of this

Regulation. As soon as possible after its completion, the

test should be validated as provided for by Regulation

Member States should perform a test on the exchange of supplementary information.

(EC) No 1987/2006 and Decision 2007/533/JHA.

⁽¹⁾ Opinion of 24 September 2008, not yet published in the Official

⁽²⁾ OJ L 239, 22.9.2000, p. 19.

⁽³⁾ OJ L 328, 13.12.2001, p. 4. (4) OJ L 328, 13.12.2001, p. 1.

⁽⁵⁾ OJ L 381, 28.12.2006, p. 4.

⁽⁶⁾ OJ L 205, 7.8.2007, p. 63.

⁽⁷⁾ OJ L 57, 1.3.2008, p. 1. (8) OJ L 57, 1.3.2008, p. 14.

- (9) In order to better manage the potential difficulties brought about by the migration from SIS 1+ to SIS II, an interim migration architecture for the Schengen Information System should be established and tested. The interim migration architecture should have no impact on the operational availability of SIS 1+. A converter should be provided by the Commission.
- (10) The Member State issuing an alert should be responsible for ensuring that the data entered into the Schengen Information System is accurate, up to date and lawful.
- (11) The Commission should remain responsible for Central SIS II and its communication infrastructure. This responsibility includes the maintenance and continuation of the development of SIS II and its communication infrastructure, including at all times the correction of errors. The Commission should provide coordination and support for the joint activities. The Commission should provide, in particular, the necessary technical and operational support to the Member States at Central SIS II level including the availability of a helpdesk.
- (12) The Member States are and should remain responsible for the development and maintenance of their national systems (N.SIS II).
- (13) France should remain responsible for the technical support function of SIS 1+, as expressly provided for in the Schengen Convention.
- (14) Representatives of the Member States participating in SIS 1+ should coordinate their actions within the framework of the Council. It is necessary to set out a framework for that organisational action.
- (15) The Commission should be empowered to contract out to third parties, including national public bodies, tasks conferred upon it by this Regulation and tasks relating to the implementation of the budget, in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (1).

Any such contract should respect the rules of data protection and data security and take into account the role of the relevant data protection authorities applicable to the SIS, in particular the provisions of the Schengen Convention and of this Regulation.

- (16) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (2) applies to the processing of personal data by the Commission.
- (17) The European Data Protection Supervisor, appointed pursuant to Decision 2004/55/EC of the European Parliament and of the Council of 22 December 2003 appointing the independent supervisory body provided for in Article 286 of the EC Treaty (3), is competent to monitor the activities of the Community institutions and bodies in relation to the processing of personal data. The Schengen Convention contains specific provisions on the protection and security of personal data.
- (18) Since the objectives of setting up the interim migration architecture and the migration of data from SIS 1+ to SIS II, cannot be sufficiently achieved by the Member States and can, therefore, by reason of the scale and effects of the action, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty establishing the European Community. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve those objectives.
- (19) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.
- (20) The Schengen Convention should be amended to allow the integration of SIS 1+ into the interim migration architecture
- (21) In accordance with Articles 1 and 2 of the Protocol on the position of Denmark annexed to the Treaty on European Union and the Treaty, Denmark does not take part in the adoption of this Regulation and is therefore not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis under the provisions of Title IV of Part Three of the Treaty establishing the European Community, Denmark should, in accordance with Article 5 of the said Protocol, decide within a period of six months after the adoption of this Regulation whether it will implement it in its national law.

⁽²⁾ OJ L 8, 12.1.2001, p. 1.

⁽³⁾ OJ L 12, 17.1.2004, p. 47.

- This Regulation constitutes a development of 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 (1); the United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.
- This Regulation constitutes a development of provisions (23)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 (2); Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application.
- This Regulation is without prejudice to the arrangements (24)for the United Kingdom's and Ireland's partial participation in the Schengen acquis as determined by Council Decisions 2000/365/EC and 2002/192/EC respectively.
- As regards Iceland and Norway, this Regulation (25)constitutes a development of provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (3), which fall within the area referred to in Article 1, point G of Council Decision 1999/437/EC (4) on certain arrangements for the application of that Agreement.
- As regards Switzerland, this Regulation constitutes a (26)development of provisions of the Schengen acquis within the meaning of the Agreement concluded the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (5), which fall within the area referred to in Article 1, point G of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC (6) on the conclusion, on behalf of the European Community, of the Agreement.
- As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen acquis

within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point G of Council Decision 1999/437/EC of 17 May 1999 read in conjunction with Article 3 of Council Decision 2008/261/EC of 28 February 2008 on the signature, on behalf of the European Community, and on the provisional application of certain provisions of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (7),

HAS ADOPTED THIS REGULATION:

Article 1

General purpose

- 1. The Schengen Information System (SIS), set up pursuant to the provisions of Title IV of the 1990 Schengen Convention (SIS 1+), shall be replaced by a new system, the Schengen Information System II (SIS II), the establishment, operation and use of which is regulated by Regulation (EC) No 1987/2006.
- 2. In accordance with the procedures and the division of tasks set out in this Regulation, SIS II shall be developed by the Commission and the Member States as a single integrated system and shall be prepared for operations.

Article 2

Definitions

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

- (a) 'Central SIS II' means the technical support function of SIS II containing a database, the 'SIS II database', and a uniform national interface (NI-SIS);
- (b) 'C.SIS' means the technical support function of SIS 1+, containing the reference database for SIS 1+ and the uniform national interface (N.COM);

⁽¹) OJ L 131, 1.6.2000, p. 43. (²) OJ L 64, 7.3.2002, p. 20. (³) OJ L 176, 10.7.1999, p. 36. (⁴) OJ L 176, 10.7.1999, p. 31. (⁵) OJ L 53, 27.2.2008, p. 52. (6) OJ L 53, 27.2.2008, p. 1.

⁽⁷⁾ OJ L 83, 26.3.2008, p. 3.

- (c) 'N.SIS' means the national system of SIS 1+, consisting of the national data systems which communicate with C.SIS;
- (d) 'N.SIS II' means the national system of SIS II, consisting of the national data systems which communicate with Central SIS II;
- (e) 'converter' means a technical tool to allow consistent and reliable communication between C.SIS and Central SIS II, ensuring the functionalities provided for in Article 10(3);
- (f) 'comprehensive test' means the test referred to in Article 55(3)(c) of Regulation (EC) No 1987/2006;
- (g) 'test on supplementary information' means functional tests between the Sirene Bureaux.

Subject matter and scope

This Regulation defines the tasks and responsibilities of the Commission and the Member States participating in SIS 1+ with respect to the following tasks:

- (a) the maintenance and continuation of the development of SIS II;
- (b) a comprehensive test of SIS II;
- (c) a test on supplementary information;
- (d) the continuation of the development and testing of a converter;
- (e) the establishment and testing of a provisional migration architecture:
- (f) the migration from SIS 1+ to SIS II.

Article 4

Technical components of the migration architecture

In order to ensure the migration from SIS 1+ to SIS II, the following components are necessary:

- (a) the C.SIS and the connection to the converter;
- (b) the communication infrastructure for SIS 1+ allowing the C.SIS to communicate with the N.SIS;
- (c) the N.SIS;
- (d) Central SIS II, NI-SIS and the communication infrastructure for SIS II allowing the Central SIS II to communicate with N.SIS II and the converter;

- (e) the N.SIS II;
- (f) the converter.

Article 5

Main responsibilities in the development of SIS II

- 1. The Commission shall continue to develop the Central SIS II, the communication infrastructure and the converter.
- 2. France shall make available and operate C.SIS in accordance with the provisions of the Schengen Convention.
- 3. The Member States shall continue to develop N.SIS II.
- 4. The Member States participating in SIS 1+ shall maintain N.SIS in accordance with the provisions of the Schengen Convention.
- 5. The Member States participating in SIS 1+ shall make available and operate the communication infrastructure for SIS 1+.
- 6. The Commission shall coordinate the activities and provide the necessary support for the implementation of the tasks and responsibilities referred to in paragraphs 1 to 3.

Article 6

Continuing development

The measures necessary to continue the development of SIS II as referred to in Article 5(1), in particular measures necessary for the correction of errors, shall be adopted in accordance with the procedure defined in Article 17(2).

The measures necessary to continue the development of SIS II as referred to in Article 5(3), insofar as it concerns the uniform national interface ensuring the compatibility of N.SIS II with Central SIS II, shall be adopted in accordance with the procedure defined in Article 17(2).

Article 7

Main activities

- 1. The Commission together with Member States participating in SIS 1+ shall conduct a comprehensive test.
- 2. An interim SIS migration architecture shall be set up and a test of that architecture shall be performed by the Commission together with France and the other Member States participating in SIS 1+.
- 3. The Commission and the Member States participating in SIS 1+ shall perform the migration from SIS 1+ to SIS II.

- 4. The Member States participating in SIS 1+ shall perform a test on the exchange of supplementary information.
- 5. The Commission shall provide the necessary support at Central SIS II level for the activities in paragraphs 1 to 4.
- 6. The activities in paragraphs 1 to 3 shall be coordinated by the Commission and the Member States participating in SIS 1+ acting within the Council.

Comprehensive test

- 1. The comprehensive test shall not start before the Commission has declared that it considers that the level of success of the tests referred to in Article 1 of Regulation (EC) No 189/2008 is sufficient to begin such a test.
- 2. A comprehensive test aiming at confirming, in particular, the completion by the Commission and the Member States participating in SIS 1+ of the necessary technical arrangements to process SIS II data and the demonstration that the level of performance of SIS II is at least equivalent to that achieved with SIS 1+ shall be performed.
- 3. The comprehensive test shall be executed by the Member States participating in SIS 1+ for the N.SIS II and by the Commission for the Central SIS II.
- 4. The comprehensive test shall follow a detailed schedule defined by Member States participating in SIS 1+ acting within the Council in cooperation with the Commission.
- 5. The comprehensive test shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council in cooperation with the Commission.
- 6. The Commission and the Member States participating in SIS 1+ acting within the Council shall define the criteria for determining whether the necessary technical arrangements to process SIS II data are completed and the level of performance of SIS II is at least equivalent to that achieved with SIS 1+.
- 7. The test results shall be analysed using the criteria mentioned in paragraph 6, by the Member States participating in SIS 1+ acting within the Council and the Commission. The test results shall be validated in accordance with Article 55(3)(c) of Regulation (EC) No 1987/2006.
- 8. Member States not participating in SIS 1+ may participate in the comprehensive test. Their results shall not affect the overall validation of the test.

Article 9

Test on supplementary information

- 1. The Member States participating in SIS 1+ shall conduct functional Sirene tests.
- 2. The Commission shall make available Central SIS II and its communication infrastructure during the execution of the test on supplementary information.
- 3. The test on supplementary information shall follow a detailed schedule defined by Member States participating in SIS 1+ acting within the Council.
- 4. The test on supplementary information shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council.
- 5. The test results shall be analysed by the Member States participating in SIS 1+ acting within the Council.
- 6. Member States not participating in SIS 1+ may participate in the test on supplementary information. Their results shall not affect the overall validation of the test.

Article 10

Interim migration architecture

- 1. An interim SIS migration architecture shall be set up. The converter connects Central SIS II and C.SIS for a transitional period. The N.SIS are connected to C.SIS, the N.SIS II to Central SIS II.
- 2. The Commission shall provide a converter, the Central SIS II and its communication infrastructure as part of the interim SIS migration architecture.
- 3. The converter shall convert data in two directions between the C.SIS and Central SIS II and keep C.SIS and Central SIS II synchronised.
- 4. The Commission shall test the communication between Central SIS II and the converter.
- 5. France shall test the communication between C.SIS and the converter.
- 6. The Commission and France shall test the communication between Central SIS II and C.SIS via the converter.
- 7. France, together with the Commission, shall connect C.SIS via the converter to Central SIS II.

- 8. The Commission, together with France and the other Member States participating in SIS 1+, shall test the interim SIS migration architecture as a whole in accordance with a test plan provided by the Commission.
- 9. France shall make available data for test purpose, if necessary.

Migration from SIS 1+ to SIS II

- 1. For the migration from C.SIS to Central SIS II, France shall make available the SIS 1+ database and the Commission shall introduce the SIS 1+ database into Central SIS II.
- 2. The Member States participating in SIS 1+ shall migrate from N.SIS to N.SIS II using the interim migration architecture, with the support of France and of the Commission, by 30 September 2009 at the latest. If necessary, this date may be changed in accordance with the procedure defined in Article 17(2).
- 3. The migration of the national system from SIS 1+ to SIS II consists of the data loading of N.SIS II, when that N.SIS II is to contain a data file, the national copy, containing a complete or partial copy of the SIS II database, followed by a switchover from N.SIS to N.SIS II for each Member State. The migration shall follow a detailed schedule provided by the Commission and the Member States participating in SIS 1+ acting within the Council.
- 4. The Commission shall assist in coordination and support of the common activities during the migration.
- 5. The switchover foreseen in the migration process shall be carried out after the validation mentioned in Article 8(7).

Article 12

Substantive legal framework

During the migration, the provisions of Title IV of the Schengen Convention shall continue to apply to the Schengen Information System.

Article 13

Cooperation

- 1. The Member States and the Commission shall cooperate for the execution of all the activities covered by this Regulation in accordance with their respective responsibilities.
- 2. The Commission shall in particular provide the necessary support at Central SIS II level for the testing and migration of N.SIS II.

3. Member States shall in particular provide the necessary support at N.SIS II level for the testing of the interim migration infrastructure.

Article 14

Keeping of records in Central SIS II

- 1. Without prejudice to the relevant provisions of Title IV of the Schengen Convention, the Commission shall ensure that every access to and all exchanges of personal data within Central SIS II are recorded for the purposes of checking whether or not the search is lawful, monitoring the lawfulness of data processing and ensuring the proper functioning of Central SIS II and of national systems, data integrity and security.
- 2. The records shall show, in particular, the date and time of the data transmitted, the data used to perform searches, the reference to the data transmitted and the name of the competent authority responsible for processing the data.
- 3. The records may only be used for the purposes referred to in paragraph 1 and shall be deleted at the earliest one year, and at the latest three years after their creation.
- 4. Records may be kept longer if they are required for monitoring procedures that are already under way.
- 5. The competent authorities in charge of checking whether or not a search is lawful, monitoring the lawfulness of data processing, self-monitoring and ensuring the proper functioning of Central SIS II, data integrity and security, shall have access, within the limits of their competence and at their request, to those records for the purpose of fulfilling their tasks.

Article 15

Costs

- 1. The costs arising from migration, the comprehensive test, the test on supplementary information, maintenance and development measures at Central SIS II level or concerning the communication infrastructure shall be borne by the general budget of the European Union.
- 2. The costs arising from migration, testing, maintenance and development of the national systems shall be borne by each Member State concerned.
- 3. The costs arising from activities at SIS 1+ level, including supplementary activities of France, acting on behalf of the Member States participating in SIS 1+, shall be borne in accordance with the provisions of Article 119 of the Schengen Convention.

Amendment of the provisions of the Schengen Convention

The provisions of the Schengen Convention are hereby amended as follows.

1. The following Article shall be inserted:

'Article 92A

- 1. As from the entry into force of Council Regulation (EC) No 1104/2008 (*) and Council Decision 2008/839/JHA (**) and relying on the definitions in Article 2 of that Regulation, the technical architecture of the Schengen Information System may be supplemented by:
- (a) an additional central system composed of:
 - technical support function (Central SIS II), located in France and backup Central SIS II located in Austria, containing the SIS II database and a uniform national interface (NI-SIS),
 - a technical connection between the C.SIS and the Central SIS II via the converter allowing the conversion and synchronisation of data between the C.SIS and the Central SIS II;
- (b) a national system (N.SIS II), consisting of the national data systems, which communicates with the Central SIS II;
- (c) an infrastructure for communication between Central SIS II and the N.SIS II connected to the NI-SIS.
- 2. The N.SIS II may replace the national section referred to in Article 92 of this Convention, in which case the Member States need not hold a national data file.
- 3. The central SIS II database shall be available for the purpose of carrying out automated searches in the territory of each Member State.
- 4. In case any of the Member States replace their national section by N.SIS II, the compulsory functions of the technical support function towards that national section as mentioned in Article 92(2) and (3) become compulsory functions towards Central SIS II, without prejudice to the obligations referred to in Decision 2008/839/JHA and in Articles 5(1), 10(1), (2) and (3) of Regulation (EC) No 1104/2008.
- 5. Central SIS II shall provide the services necessary for the entry and processing of SIS data, the online update of N.SIS II national copies, the synchronisation of and consistency between N.SIS II national copies and the

Central SIS II database and provide operations for initialisation and restoration of N.SIS II national copies.

6. France, responsible for the technical support function, the other Member States and the Commission shall cooperate to ensure that a search in the data files of N.SIS II or in the SIS II database produces a result equivalent to that of a search in the data file of the national sections referred to in Article 92(2).

- (*) OJ L 299, 8.11.2008, p. 1. (**) OJ L 299, 8.11.2008, p. 43.
- 2. In Article 119 first paragraph, the first sentence shall be replaced by the following:

The costs of installing and operating the technical support function referred to in Article 92(3), including the cost of lines connecting the national sections of the Schengen Information System to the technical support function, and of activities performed in conjunction with tasks conferred upon France in application of Decision (JHA) 2008/839/JHA and of Regulation (EC) No 1104/2008 shall be borne jointly by the Member States.'

3. In Article 119, the second paragraph shall be replaced by the following:

The costs of installing and operating the national section of the Schengen Information System and of tasks conferred upon national systems under Decision 2008/839/JHA and Regulation (EC) No 1104/2008 shall be borne by each Member State individually.'

Article 17

Committee

- 1. The Commission shall be assisted by the Committee established by Article 51 of Regulation (EC) No 1987/2006.
- 2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 18

Reporting

The Commission shall submit by the end of every six month period, and for the first time by the end of the first six month period of 2009, a progress report to the European Parliament and the Council concerning the development of SIS II and the migration from SIS 1+ to SIS II.

Entry into force and applicability

This Regulation shall enter into force on the third day following its publication in the Official Journal of the European Union. It shall expire on a date to be fixed by the Council, acting in accordance with Article 55(2) of Regulation (EC) No 1987/2006, and in any case no later than on 30 June 2010.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaty establishing the European Community.

Done at Luxembourg, 24 October 2008.

For the Council
The President
M. ALLIOT-MARIE

COMMISSION REGULATION (EC) No 1105/2008

of 7 November 2008

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

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

Whereas:

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 8 November 2008.

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

Done at Brussels, 7 November 2008.

For the Commission

Jean-Luc DEMARTY

Director-General for Agriculture and

Rural Development

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

 $\label{eq:annex} ANNEX$ 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 | MA | 48,3 |
| | MK | 46,2 |
| | TR | 68,6 |
| | ZZ | 54,4 |
| 0707 00 05 | JO | 175,3 |
| | MA | 30,8 |
| | TR | 90,7 |
| | ZZ | 98,9 |
| 0709 90 70 | MA | 63,1 |
| | TR | 129,7 |
| | ZZ | 96,4 |
| 0805 20 10 | MA | 80,7 |
| | ZZ | 80,7 |
| 0805 20 30, 0805 20 50, 0805 20 70, | HR | 24,7 |
| 0805 20 90 | MA | 85,5 |
| | TR | 79,5 |
| | ZZ | 63,2 |
| 0805 50 10 | AR | 82,1 |
| | MA | 103,9 |
| | TR | 91,1 |
| | ZA | 97,2 |
| | ZZ | 93,6 |
| 0806 10 10 | BR | 232,5 |
| | TR | 133,5 |
| | US | 246,0 |
| | ZA | 197,4 |
| | ZZ | 202,4 |
| 0808 10 80 | AL | 32,1 |
| | AR | 75,0 |
| | CA | 96,3 |
| | CL | 64,2 |
| | MK | 37,6 |
| | NZ | 104,3 |
| | US | 162,4 |
| | ZA | 87,6 |
| | ZZ | 82,4 |
| 0808 20 50 | CN | 44,4 |
| | TR | 124,9 |
| | ZZ | 84,7 |

⁽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'.

COMMISSION REGULATION (EC) No 1106/2008

of 7 November 2008

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EC) No 945/2008 for the 2008/2009 marketing year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector (²), and in particular Article 36(2), second subparagraph, second sentence thereof.

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups

for the 2008/2009 marketing year are fixed by Commission Regulation (EC) No 945/2008 (³). These prices and duties have been last amended by Commission Regulation (EC) No 1084/2008 (4).

(2) The data currently available to the Commission indicate that those amounts should be amended in accordance with the rules and procedures laid down in Regulation (EC) No 951/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EC) No 945/2008 for the 2008/2009, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 8 November 2008.

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

Done at Brussels, 7 November 2008.

For the Commission
Jean-Luc DEMARTY
Director-General for Agriculture and
Rural Development

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 178, 1.7.2006, p. 24.

⁽³⁾ OJ L 258, 26.9.2008, p. 56.

⁽⁴⁾ OJ L 297, 6.11.2008, p. 3.

ANNEX Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 8 November 2008

(EUR)

| CN code | Representative price per 100 kg net of the product concerned | Additional duty per 100 kg net of the product concerned |
|----------------|--|---|
| 1701 11 10 (¹) | 24,58 | 4,01 |
| 1701 11 90 (1) | 24,58 | 9,24 |
| 1701 12 10 (1) | 24,58 | 3,82 |
| 1701 12 90 (1) | 24,58 | 8,81 |
| 1701 91 00 (²) | 25,74 | 12,39 |
| 1701 99 10 (²) | 25,74 | 7,84 |
| 1701 99 90 (²) | 25,74 | 7,84 |
| 1702 90 95 (3) | 0,26 | 0,39 |

⁽¹) For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007. (²) For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007. (³) Per 1 % sucrose content.

COMMISSION REGULATION (EC) No 1107/2008

of 7 November 2008

amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I and IV thereto to technical progress

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (1), and in particular Article 31(1) and (3) thereof.

Whereas:

- (1) Article 3 of Regulation (EC) No 2003/2003 provides that a fertiliser belonging to a type of fertiliser listed in Annex I thereto and complying with the conditions laid down in that Regulation may be designated 'EC fertiliser'.
- (2) Ammonium sulphate and calcium nitrate (nitrate of lime) are both listed as fertiliser types in Annex I to Regulation (EC) No 2003/2003. However, combinations of those two fertiliser types may not be designated 'EC fertiliser'. As combinations of ammonium sulphate and calcium nitrate (nitrate of lime) have been used successfully in two Member States, such combinations should be recognised as 'EC fertilisers' so that they can be made more easily available to farmers throughout the Community.
- (3) Many of the primary nutrient fertiliser types containing nitrogen that are listed in Annex I tend to release their nitrogen too rapidly for crops to benefit fully from it, and as a result the excess nitrogen may potentially cause harm to the environment.
- (4) As regards two EC fertiliser types listed in Annex I to Regulation (EC) No 2003/2003, the addition of dicyandiamide, one of a number of substances known as nitrification inhibitors, may prevent any such potential harm to the environment. Other types of EC fertiliser may contain nitrogen in a different form for which nitrification inhibitors are not effective. For those other types, urease inhibitors may offer a satisfactory solution.

- (5) To allow greater access to the agronomic and environmental benefits of nitrification or urease inhibitors, the use of nitrification or urease inhibitors should be allowed for most types of nitrogen fertilisers, and more types of inhibitors should be allowed.
- (6) A list of authorised nitrification and urease inhibitors should therefore be introduced in Annex I to Regulation (EC) No 2003/2003.
- (7) Annex IV to Regulation (EC) No 2003/2003 provides detailed descriptions of the methods of analysis to be used to measure the nutrient content of EC fertilisers. Those descriptions, insofar as they concern iodine concentration, need to be adjusted in order to have correct analysis values.
- (8) Regulation (EC) No 2003/2003 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 32 of Regulation (EC) No 2003/2003,

HAS ADOPTED THIS REGULATION:

Article 1

- 1. Annex I to Regulation (EC) No 2003/2003 is amended in accordance with Annex I to this Regulation.
- 2. Annex IV to Regulation (EC) No 2003/2003 is amended in accordance with Annex II to this Regulation.

Article 2

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

⁽¹⁾ OJ L 304, 21.11.2003, p. 1.

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

Done at Brussels, 7 November 2008.

For the Commission Günter VERHEUGEN Vice-President

ANNEX I

Annex I to Regulation (EC) No 2003/2003 is amended as follows:

(1) in Table A.1, the entry for fertiliser type 4 'sulphate of ammonia' is replaced by the following:

| '4 | Sulphate of ammonia | Chemically obtained product containing ammonium sulphate as its essential ingredient, possibly with up to 15 % calcium nitrate (nitrate of lime). | Nitrogen expressed as total nitrogen. Maximum content of nitric | (nitrate of lime), the designation must include "with up to 15% calcium nitrate | Total nitrogen if calciur nitrate (nitrate of lime) added' |
|----|---------------------|---|--|---|--|
|----|---------------------|---|--|---|--|

- (2) in Table A.1, the entries for fertiliser types 16, 17 and footnote (a) are deleted. Type 18 becomes type 16:
- (3) the following Section F is added:

'F. Nitrification and urease inhibitors

The urease and nitrification inhibitors listed in the Tables F.1. and F.2. below may be added to the nitrogenous fertilisers types listed in Sections A.1., B.1., B.2., B.3., C.1. and C.2. of Annex I subject to the following provisions:

- (1) at least 50 % of the total nitrogen content of the fertiliser consists of the nitrogen forms specified in column 3;
- (2) they do not belong to the fertiliser types mentioned in column 4.

Fertilisers to which a nitrification inhibitor listed in Table F.1. has been added shall have the words "with nitrification inhibitor ([type designation of nitrification inhibitor])" added to their type designation.

Fertilisers to which a urease inhibitor listed in Table F.2. has been added shall have the words "with urease inhibitor ([type designation of urease inhibitor])" added to their type designation.

Technical information, as complete as possible, must be provided with each package or bulk consignment by the person responsible for marketing. This information must enable the user in particular to determine the rates and timing of application in relation to the crop being grown.

New nitrification inhibitors or urease inhibitors may be included in the Tables F1 or F2 respectively after evaluation of the technical files submitted in accordance with guidelines to be elaborated for these compounds.

F.1. Nitrification inhibitors

| No | Type designation and composition of the nitrification inhibitor | Minimum and maximum inhibitor content as a percentage by mass of the total nitrogen present as ammonium nitrogen and urea nitrogen. | EC fertiliser types for which the inhibitor may not be used | Description of nitrification inhibitors with which mixtures are allowed Data on permitted ratio |
|----|---|---|---|--|
| 1 | 2 | 3 | 4 | 5 |
| 1 | Dicyandiamide Minimum 2,25 ELINCS No 207-312-8 Maximum 4,5 | | | |

F.2. Urease inhibitors

| No | Type designation and composition of the urease inhibitor | Minimum and maximum inhibitor content as a percentage by mass of the total nitrogen present as urea nitrogen | | Description of urease inhibitors with which mixtures are allowed Data on permitted ratio |
|----|--|--|---|---|
| 1 | 2 | 3 | 4 | 5 |
| 1 | N-(n-butyl) thiophosphoric triamide (NBPT) ELINCS No 435-740-7 | Minimum 0,09 Maximum 0,20' | | |

ANNEX II

Section B of Annex IV to Regulation (EC) No 2003/2003 is amended as follows:

(1) in the note in point 4.11. of Method 2.3.2, the second, third and fourth subparagraphs are replaced by the following:

'Titrate with 0,05 mol/l iodine (I2) solution in the presence of a starch solution as an indicator.

1 ml of iodine (I_2) solution 0,05 mol/l corresponds to 0,01128 g of SnCl₂·2H₂O.

At least 80 % of the total tin present in the solution thus prepared must be in a bivalent form. For the titration at least 35 ml of 0.05 mol/l iodine (I_2) solution must be used.'

(2) in the note in point 4.11. of Method 2.6.1, the second, third and fourth subparagraphs are replaced by the following:

Titrate with 0.05 mol/l iodine (I_2) solution in the presence of a starch solution as an indicator.

1 ml of iodine (I2) solution 0,05 mol/l corresponds to 0,01128 g of SnCl2 \cdot 2H2O.

At least 80 % of the total tin present in the solution thus prepared must be in a bivalent form. For the titration at least 35 ml of 0.05 mol/l iodine (I_2) solution must be used.'

COMMISSION REGULATION (EC) No 1108/2008

of 7 November 2008

amending Regulation (EC) No 1266/2007 as regards the minimum requirements for bluetongue monitoring and surveillance programmes and the conditions for exempting semen from the exit ban provided for in Council Directive 2000/75/EC

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (1), and in particular, Articles 11 and 12 and the third paragraph of Article 19 thereof.

Whereas:

- (1) Directive 2000/75/EC lays down control rules and measures to combat and eradicate bluetongue. They include the establishment of protection and surveillance zones ('restricted zones'), the implementation of bluetongue monitoring and surveillance programmes, and an exit ban on animals leaving the restricted zones ('the exit ban').
- (2) Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue (²) lays down rules to be applied in the event of an outbreak of that disease.
- (3) Annex I to Regulation (EC) No 1266/2007 sets out the minimum requirements for the bluetongue monitoring and surveillance programmes. Annex III to that Regulation sets out the conditions for exemption from the exit ban with regard to animals, their semen, ova and embryos. Annex V to that Regulation sets out criteria for the purpose of determining a bluetongue seasonally-free zone.
- (4) It is essential that appropriate bluetongue monitoring and surveillance programmes are in place to achieve, among others, the objectives of the detection of the presence of the bluetongue virus at the earliest possible stage, to demonstrate the absence of general or specific bluetongue virus serotypes, and for the determination of the seasonally vector-free period. The bluetongue monitoring and surveillance programmes should include

minimum requirements for Member States, while ensuring sufficient flexibility to take account of local epidemiological conditions.

- (5) A mass emergency vaccination campaign against various types of bluetongue is being implemented in the EU. The vaccination of animals against that disease represents a major change of the immune status of the susceptible species population and has implications for bluetongue surveillance and monitoring programmes. Therefore, certain modifications to the requirements for the programmes need to be made.
- (6) Annex V to Regulation (EC) No 1266/2007 sets out criteria for the purpose of determining a bluetongue seasonally-free zone. For reasons of clarification and a more harmonized approach, the beginning and the end of the seasonally vector-free period should be based on standardized surveillance data.
- (7) Section B of Annex III to Regulation (EC) No 1266/2007 sets out conditions for exemption from the exit ban with regard to semen. It provides that semen must have been obtained from donor animals which comply with certain conditions, in order to be exempted. In the interests of certainty of Community legislation, it is appropriate to clarify certain requirements as regards the testing regimes of semen donor animals, in particular as regards post-collection testing.
- (8) Regulation (EC) No 1266/2007 should therefore be amended accordingly.
- (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

Regulation (EC) No 1266/2007 is amended as follows:

1. Annex I is replaced by the text in the Annex to this Regulation;

⁽¹⁾ OJ L 327, 22.12.2000, p. 74.

⁽²⁾ OJ L 283, 27.10.2007, p. 37.

- 2. in Section B of Annex III, points (d) and (e) are replaced by the following:
 - '(d) they have been subjected to a serological test according to the OIE Terrestrial Manual to detect antibodies to the bluetongue virus group, with negative results, at least every 60 days during the collection period and between 21 and 60 days following the final collection of the semen to be consigned;
 - (e) they have been subjected, with negative results, to an agent identification test according to the OIE Terrestrial Manual carried out on blood samples collected:
 - (i) at commencement and final collection of the semen to be consigned; and

- (ii) during the period of semen collection:
 - at least every seven days, in the case of a virus isolation test, or
 - at least every 28 days, in the case of a polymerase chain reaction test.'

This Regulation shall enter into force on the 20th 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, 7 November 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

'ANNEX I

Minimum requirements for bluetongue monitoring and surveillance programmes (referred to in Article 4)

1. Minimum requirements for bluetongue monitoring programmes to be implemented by Member States in restricted zones

Bluetongue monitoring programmes shall be aimed at providing information on the dynamics of bluetongue in a restricted zone. The objectives of bluetongue monitoring programmes are to detect the introduction of new bluetongue serotypes and to demonstrate the absence of certain bluetongue serotypes. Other objectives may include the demonstration of the absence of bluetongue virus circulation, the determination of the seasonally vector free period and identifying the vector species.

The geographical unit of reference for the purposes of bluetongue monitoring and surveillance shall be defined by a grid of around 45×45 km (approximately 2 000 km²) unless specific environmental conditions justify a different size. Member States may also use the "region" as defined in Article 2(p) of Directive 64/432/EEC as the geographical unit of reference for monitoring and surveillance purposes.

- 1.1. Bluetongue monitoring programmes shall consist of at least passive clinical surveillance and active laboratory-based surveillance, as set out in points 1.1.1 and 1.1.2.
- 1.1.1. Passive clinical surveillance shall:
 - consist of a formal and properly documented ongoing system aimed at detecting and investigating any suspicions, including an early warning system for reporting suspicions. Owners or holders and veterinarians must promptly report any suspicion to the competent authority. All suspicions due to the presence of bluetongue serotypes not expected to be present in the epidemiologically relevant geographical area must be thoroughly investigated immediately by the competent authority in order to ascertain the bluetongue serotypes circulating;
 - be specially reinforced during the season of vector activity;
 - ensure that awareness campaigns are put in place and aimed, in particular, at enabling owners or holders and veterinarians in identifying clinical signs of bluetongue.
- 1.1.2. Active laboratory-based surveillance shall consist of at least one, or a combination of, serological monitoring with sentinel animals, serological/virological surveys, or targeted risk-based monitoring, as set out in points 1.1.2.1, 1.1.2.2 and 1.1.2.3.
- 1.1.2.1. Serological monitoring with sentinel animals:
 - Serological monitoring with sentinel animals shall consist of an active annual programme of testing sentinel animals aimed at assessing the circulation of the bluetongue virus within the restricted zone. Where possible, sentinel animals must be bovine animals. They must be free from antibodies as demonstrated by means of a preliminary seronegative test and must be located in areas of the restricted zone where, following a risk analysis considering entomological and ecological evaluations, the presence of the vector has been confirmed or habitats suitable for the vector's breeding are present;
 - Sentinel animals shall be tested at least once a month during the period of activity of the vector involved, if known. In the absence of such information the sentinel animals shall be tested at least once a month throughout the year;
 - The minimum number of sentinel animals per geographical unit of reference for the purposes of bluetongue monitoring and surveillance must be representative and sufficient in order to detect a monthly incidence of seroconversion (1) of 2 % with 95 % confidence in each geographical unit of reference;
 - Laboratory testing shall be designed in such a way that positive screening tests are followed by the specific serotype serological/virological tests targeted to the bluetongue serotype or serotypes expected to be present in the epidemiologically relevant geographical area necessary to ascertain the specific serotype circulating.

⁽¹⁾ It has been estimated that 20 % is the normal annual rate of seroconversion in an infected zone. However, in the Community, virus circulation mainly takes place in a period of around six months (end of spring/mid autumn). Therefore 2 % is a conservative estimation of the expected monthly rate of seroconversion.

1.1.2.2. Serological/virological surveys:

- shall consist of at least an active annual programme of serological/virological testing of susceptible species populations, aimed at detecting evidence of bluetongue virus transmission through random serological and/or virological testing implemented in all epidemiologically relevant geographical areas and performed in the period of the year when seroconversion is more likely to be detected;
- must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 20 % with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area;
- must ensure that seropositive animals from vaccinated or immunized populations do not interfere with the serological surveys;
- must ensure that laboratory testing is designed in such a way that positive screening tests are followed by the specific serotype serological/virological tests targeted to the bluetongue serotype or serotypes expected to be present in the epidemiologically relevant geographical area necessary to ascertain the specific serotype circulating;
- may also be designed to monitor vaccination coverage and distribution of different bluetongue serotypes present in the restricted zone.

1.1.2.3. Targeted risk-based monitoring:

- shall consist of a formal and properly documented ongoing system aimed at demonstrating the absence of certain specific bluetongue serotypes;
- applies to a target population of susceptible animals at a relative high risk, based on their location, the geographical situation and the epidemiology of the bluetongue serotype or serotypes expected to be present in the epidemiologically relevant geographical area;
- must have a sampling strategy that is adjusted to the defined target population. The sample size has been calculated to detect the design prevalence (based on the known risk of the target population) with 95 % confidence in the target population of that epidemiologically relevant geographical area. Whenever the samples do not originate from individual animals, sample size must be adjusted according to the sensitivity of the diagnostic procedures applied.
- 1.2. To determine the seasonally vector-free period as referred to in Annex V to this Regulation, entomological surveillance must meet the following requirements:
 - it shall consist of at least an active annual programme of vector catching by means of permanently sited aspiration traps intended to determine the population dynamics of the vector;
 - aspiration traps equipped with ultraviolet light must be used in accordance with pre-established protocols. The traps must be operated throughout the night and operate at a rate of at least:
 - one night per week during the month before the expected beginning and during the month before the expected end of the seasonally vector-free period;
 - one night per month during the seasonally vector-free period;
 - on the basis of the evidence obtained in the three first years of their operation, the frequency of operation of the aspiration traps may be adjusted;
 - at least one aspiration trap must be placed in each epidemiologically relevant area all over the bluetongue seasonally-free zone. A proportion of the midges collected in the aspiration traps must be sent to a specialised laboratory capable of counting and identifying the suspected vector species.

- 1.3. Monitoring in order to provide the Commission with substantiated information demonstrating the absence of bluetongue virus circulation in an epidemiological relevant geographical area during a period of two years, as referred to in Article 6(2):
 - shall consist of at least one, or a combination of, serological monitoring with sentinel animals, serological/virological surveys and targeted risk-based monitoring, as set out in points 1.1.2.1, 1.1.2.2 and 1.1.2.3;
 - must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 20 % (¹) with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area if mass vaccination has not been implemented; or
 - must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 10 % (²) with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area if mass vaccination has been implemented.
- 2. Minimum requirements for bluetongue surveillance programmes to be implemented by the Member States outside restricted

Bluetongue surveillance programmes shall be aimed at detecting any possible incursions of the bluetongue virus and at demonstrating the absence of that virus in a bluetongue-free Member State or epidemiologically relevant geographical area.

Bluetongue surveillance programmes shall consist of at least passive clinical surveillance and active laboratory-based surveillance, as set out in points 2.1 and 2.2.

2.1. Passive clinical surveillance:

- shall consist of a formal and properly documented ongoing system aimed at detecting and investigating any suspicions including an early warning system for reporting suspicions. Owners or holders and veterinarians must promptly report any suspicion to the competent authority. All suspicions must be thoroughly investigated by the competent authority immediately in order to confirm or rule out any outbreak of bluetongue;
- must be specially reinforced during the season of vector activity in areas having a specific relative higher risk, based on geographical and epidemiological data;
- must ensure that awareness campaigns are put in place and aimed, in particular, at enabling owners or holders and veterinarians in identifying clinical signs of bluetongue.
- 2.2. Active laboratory-based surveillance shall consist of at least one, or a combination of serological monitoring with sentinel animals, or serological/virological surveys, or targeted risk-based surveillance, as set out in points 2.2.1, 2.2.2 and 2.2.3.
- 2.2.1. Serological monitoring with sentinel animals
 - Serological monitoring with sentinel animals shall consist of an active annual programme of testing sentinel animals, aimed at detecting the evidence of bluetongue virus transmission outside the restricted zones. Specific attention must be given to areas at high risk, based on geographical and epidemiological data;
 - Sentinel animals shall be tested at least once a month during the period of activity of the vector involved, if
 that period is known. In the absence of such information, the sentinel animals shall be tested at least once a
 month throughout the year;

 ⁽¹) It has been estimated that 20 % is the normal annual rate of seroconversion in an infected zone. However, if there is evidence that the annual rate of seroconversion in the epidemiologically relevant geographical area is lower than 20 % the sample size has to be calculated to detect the lower estimated prevalence.
 (²) It has been assumed that 10 % is the normal annual rate of seroconversion in a vaccinated zone. However, if there is evidence that the

⁽²⁾ It has been assumed that 10 % is the normal annual rate of seroconversion in a vaccinated zone. However, if there is evidence that the annual rate of seroconversion in the epidemiologically relevant vaccinated geographical area is lower than 10 % the sample size has to be calculated to detect the lower estimated prevalence.

— The minimum number of sentinel animals per geographical unit of reference for the purposes of bluetongue monitoring and surveillance must be representative and sufficient in order to detect a monthly incidence of seroconversion (¹) of 2 % with 95 % confidence in each geographical unit of reference.

2.2.2. Serological/virological surveys:

- shall consist of at least an active annual programme of serological/virological testing of susceptible species populations, aimed at detecting evidence of the bluetongue virus transmission outside the restricted zones through random serological and/or virological testing implemented in all epidemiologically relevant geographical areas and performed in the period of the year when seroconversion is most likely to be detected;
- must be designed in such a way that the samples are representative and adjusted to the structure of the susceptible species population to be sampled in the epidemiologically relevant geographical area and the sample size has been calculated to detect a prevalence of 20 % with 95 % confidence in the susceptible species population of that epidemiologically relevant geographical area;
- must ensure that seropositive animals from vaccinated or immunized populations do not interfere with the serological surveys.

2.2.3. Targeted risk-based surveillance

- shall consist of a formal and well documented ongoing system aimed at demonstrating the absence of certain specific bluetongue serotypes;
- must be based on substantial knowledge of the local risk factors; such knowledge must allow the identification of the specific relative higher risk target population to be sampled;
- must ensure that the targeted sampling strategy is adjusted to the target population defined at relative higher risk and the sample size has been calculated to detect the design prevalence (based on the known risk of the target population) with 95 % confidence in the target population of that epidemiologically relevant geographical area.

⁽¹⁾ It has been estimated that 20 % is the normal annual rate of seroconversion in an infected zone. However, in the Community, virus circulation mainly takes place in a period of around six months (end of spring/mid autumn). Therefore 2 % is a conservative estimation of the expected monthly rate of seroconversion.'

COMMISSION REGULATION (EC) No 1109/2008

of 6 November 2008

amending for the 100th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with Usama bin Laden, the Al-Qaida network and the Taliban

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with Usama bin Laden, the Al-Qaida network and the Taliban, and repealing Council Regulation (EC) No 467/2001 prohibiting the export of certain goods and services to Afghanistan, strengthening the flight ban and extending the freeze of funds and other financial resources in respect of the Taliban of Afghanistan (¹), and in particular Article 7(1), first indent, thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 10 October 2008, the Sanctions Committee of the United Nations Security Council decided to amend the list of persons, groups and entities to whom the freezing of funds and economic resources should apply, by adding three persons to the list given the information related to their association with Al-Qaida.

- (3) Annex I should be amended accordingly.
- (4) In order to ensure that the measures provided for in this Regulation are effective, this Regulation must enter into force immediately.
- (5) The Commission will communicate the grounds on which this Regulation is based to the individuals concerned, provide them with the opportunity to comment on these grounds and review this Regulation in view of the comments and possible available additional information,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is hereby amended 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.

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

Done at Brussels, 6 November 2008.

For the Commission
Benita FERRERO-WALDNER
Member of the Commission

ANNEX

Annex I to Regulation (EC) No 881/2002 is amended as follows:

The following entries shall be added under the heading 'Natural persons':

- 1. Adil Muhammad Mahmud **Abd Al-Khaliq** (alias (a) Adel Mohamed Mahmoud Abdul Khaliq; (b) Adel Mohamed Mahmood Abdul Khaled). Date of birth: 2.3.1984. Place of birth: Bahrain. Passport No: 1632207 (Bahrain). Other information: (a) Has acted on behalf of and provided financial, material and logistical support to Al-Qaida and the Libyan Islamic Fighting Group, including provision of electrical parts used in explosives, computers, GPS devices and military equipment. (b) Trained by Al-Qaida in small arms and explosives in South Asia and fought with Al-Qaida in Afghanistan. (c) Arrested in the United Arab Emirates (UAE) in January 2007 on charges of being a member of Al-Qaida and the Libyan Islamic Fighting Group. (d) Following his conviction in the United Arab Emirates in late 2007, he was transferred to Bahrain in early 2008 to serve out the remainder of his sentence.
- 2. Abd Al-Rahman Muhammad Jaffar Ali (alias (a) Abd al-Rahman Muhammad Jaffir; (b) Abd al-Rahman Muhammad Jaffir Ali; (c) Abd al-Rahman Jaffir Ali; (d) Abdul Rahman Mohamed Jaffer Ali; (e) Abdulrahman Mohammad Jaffar; (f) Ali Al-Khal; (g) Abu Muhammad Al-Khal). Date of birth: 15.1.1968. Place of birth: Muharraq, Bahrain. Nationality: Bahraini. Other information: (a) Bahrain-based financier and facilitator for Al-Qaida. (b) In January 2008, convicted by the Bahraini High Criminal Court for financing terrorism, undergoing terrorist training, facilitating the travel of others to receive terrorist training abroad, and for membership in a terrorist organization. Released after Court verdict and completion of his sentence. (c) Located in Bahrain (May 2008).
- 3. Khalifa: Muhammad Turki Al-Subaiy (alias (a) Khalifa Mohd Turki Alsubaie; (b) Khalifa Mohd Turki al-Subaie; (c) Khalifa Al-Subayi; (d) Khalifa Turki bin Muhammad bin al-Suaiy). Date of birth: 1.1.1965. Nationality: Qatari. Passport No: 00685868 (Qatar). Identity card number: 26563400140 (Qatar). Other information: (a) Qatar-based terrorist financier and facilitator who has provided financial support to, and acted on behalf of, the senior leadership of Al-Qaida, including moving recruits to Al-Qaida training camps in South Asia. (b) In Jan. 2008, convicted in absentia by the Bahraini High Criminal Court for financing terrorism, undergoing terrorist training, facilitating the travel of others to receive terrorist training abroad, and for membership in a terrorist organization. (c) Arrested in Qatar in March 2008. Serving his sentence in Qatar (June 2008).

DIRECTIVES

DIRECTIVE 2008/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 October 2008

to approximate the laws of the Member States relating to trade marks

(Codified version)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

may afford to undertakings wishing to acquire trade marks

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (2),

Whereas:

- (1) The content of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (3) has been amended (4). In the interests of clarity and rationality the said Directive should be codified.
- (2) The trade mark laws applicable in the Member States before the entry into force of Directive 89/104/EEC contained disparities which may have impeded the free movement of goods and freedom to provide services and may have distorted competition within the common market. It was therefore necessary to approximate the laws of the Member States in order to ensure the proper functioning of the internal market.
- (3) It is important not to disregard the solutions and advantages which the Community trade mark system

- (4) It does not appear to be necessary to undertake full-scale approximation of the trade mark laws of the Member States. It will be sufficient if approximation is limited to those national provisions of law which most directly affect the functioning of the internal market.
- (5) This Directive should not deprive the Member States of the right to continue to protect trade marks acquired through use but should take them into account only in regard to the relationship between them and trade marks acquired by registration.
- (6) Member States should also remain free to fix the provisions of procedure concerning the registration, the revocation and the invalidity of trade marks acquired by registration. They can, for example, determine the form of trade mark registration and invalidity procedures, decide whether earlier rights should be invoked either in the registration procedure or in the invalidity procedure or in both and, if they allow earlier rights to be invoked in the registration procedure, have an opposition procedure or an *ex officio* examination procedure or both. Member States should remain free to determine the effects of revocation or invalidity of trade marks.
- (7) This Directive should not exclude the application to trade marks of provisions of law of the Member States other than trade mark law, such as the provisions relating to unfair competition, civil liability or consumer protection.
- (8) Attainment of the objectives at which this approximation of laws is aiming requires that the conditions for obtaining and continuing to hold a registered trade mark be, in general, identical in all Member States. To this end, it is necessary to list examples of signs which may constitute a trade mark, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings. The grounds for refusal or invalidity concerning the trade

⁽¹⁾ OJ C 161, 13.7.2007, p. 44.

⁽²⁾ Opinion of the European Parliament of 19 June 2007 (OJ C 146 E, 12.6.2008, p. 76) and Council Decision of 25 September 2008.

⁽³⁾ OJ L 40, 11.2.1989, p. 1.

⁽⁴⁾ See Annex I, Part A.

mark itself, for example, the absence of any distinctive character, or concerning conflicts between the trade mark and earlier rights, should be listed in an exhaustive manner, even if some of these grounds are listed as an option for the Member States which should therefore be able to maintain or introduce those grounds in their legislation. Member States should be able to maintain or introduce into their legislation grounds of refusal or invalidity linked to conditions for obtaining and continuing to hold a trade mark for which there is no provision of approximation, concerning, for example, the eligibility for the grant of a trade mark, the renewal of the trade mark or rules on fees, or related to the noncompliance with procedural rules.

- In order to reduce the total number of trade marks (9)registered and protected in the Community and, consequently, the number of conflicts which arise between them, it is essential to require that registered trade marks must actually be used or, if not used, be subject to revocation. It is necessary to provide that a trade mark cannot be invalidated on the basis of the existence of a non-used earlier trade mark, while the Member States should remain free to apply the same principle in respect of the registration of a trade mark or to provide that a trade mark may not be successfully invoked in infringement proceedings if it is established as a result of a plea that the trade mark could be revoked. In all these cases it is up to the Member States to establish the applicable rules of procedure.
- (10) It is fundamental, in order to facilitate the free movement of goods and services, to ensure that registered trade marks enjoy the same protection under the legal systems of all the Member States. This should not, however, prevent the Member States from granting at their option extensive protection to those trade marks which have a reputation.
- The protection afforded by the registered trade mark, the (11)function of which is in particular to guarantee the trade mark as an indication of origin, should be absolute in the case of identity between the mark and the sign and the goods or services. The protection should apply also in the case of similarity between the mark and the sign and the goods or services. It is indispensable to give an interpretation of the concept of similarity in relation to the likelihood of confusion. The likelihood of confusion, the appreciation of which depends on numerous elements and, in particular, on the recognition of the trade mark on the market, the association which can be made with the used or registered sign, the degree of similarity between the trade mark and the sign and between the goods or services identified, should constitute the specific condition for such protection. The ways in which likelihood of confusion may be established, and in particular the onus of proof, should be a matter for national procedural rules which should not be prejudiced by this Directive.

- (12) It is important, for reasons of legal certainty and without inequitably prejudicing the interests of a proprietor of an earlier trade mark, to provide that the latter may no longer request a declaration of invalidity nor may he oppose the use of a trade mark subsequent to his own of which he has knowingly tolerated the use for a substantial length of time, unless the application for the subsequent trade mark was made in bad faith.
- (13) All Member States are bound by the Paris Convention for the Protection of Industrial Property. It is necessary that the provisions of this Directive should be entirely consistent with those of the said Convention. The obligations of the Member States resulting from that Convention should not be affected by this Directive. Where appropriate, the second paragraph of Article 307 of the Treaty should apply.
- (14) This Directive should be without prejudice to the obligations of the Member States relating to the time limit for transposition into national law of Directive 89/104/EEC set out in Annex I, Part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Scope

This Directive shall apply to every trade mark in respect of goods or services which is the subject of registration or of an application in a Member State for registration as an individual trade mark, a collective mark or a guarantee or certification mark, or which is the subject of a registration or an application for registration in the Benelux Office for Intellectual Property or of an international registration having effect in a Member State.

Article 2

Signs of which a trade mark may consist

A trade mark may consist of any signs capable of being represented graphically, particularly words, including personal names, designs, letters, numerals, the shape of goods or of their packaging, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings.

Article 3

Grounds for refusal or invalidity

- 1. The following shall not be registered or, if registered, shall be liable to be declared invalid:
- (a) signs which cannot constitute a trade mark;

- (b) trade marks which are devoid of any distinctive character;
- (c) trade marks which consist exclusively of signs or indications which may serve, in trade, to designate the kind, quality, quantity, intended purpose, value, geographical origin, or the time of production of the goods or of rendering of the service, or other characteristics of the goods or services;
- (d) trade marks which consist exclusively of signs or indications which have become customary in the current language or in the bona fide and established practices of the trade;
- (e) signs which consist exclusively of:
 - (i) the shape which results from the nature of the goods themselves;
 - (ii) the shape of goods which is necessary to obtain a technical result;
 - (iii) the shape which gives substantial value to the goods;
- (f) trade marks which are contrary to public policy or to accepted principles of morality;
- (g) trade marks which are of such a nature as to deceive the public, for instance as to the nature, quality or geographical origin of the goods or service;
- (h) trade marks which have not been authorised by the competent authorities and are to be refused or invalidated pursuant to Article 6 ter of the Paris Convention for the Protection of Industrial Property, hereinafter referred to as the 'Paris Convention'.
- 2. Any Member State may provide that a trade mark shall not be registered or, if registered, shall be liable to be declared invalid where and to the extent that:
- (a) the use of that trade mark may be prohibited pursuant to provisions of law other than trade mark law of the Member State concerned or of the Community;
- (b) the trade mark covers a sign of high symbolic value, in particular a religious symbol;
- (c) the trade mark includes badges, emblems and escutcheons other than those covered by Article 6 *ter* of the Paris Convention and which are of public interest, unless the consent of the competent authority to their registration has been given in conformity with the legislation of the Member State;

- (d) the application for registration of the trade mark was made in bad faith by the applicant.
- 3. A trade mark shall not be refused registration or be declared invalid in accordance with paragraph 1(b), (c) or (d) if, before the date of application for registration and following the use which has been made of it, it has acquired a distinctive character. Any Member State may in addition provide that this provision shall also apply where the distinctive character was acquired after the date of application for registration or after the date of registration.
- 4. Any Member State may provide that, by derogation from paragraphs 1, 2 and 3, the grounds of refusal of registration or invalidity in force in that State prior to the date of entry into force of the provisions necessary to comply with Directive 89/104/EEC, shall apply to trade marks for which application has been made prior to that date.

Further grounds for refusal or invalidity concerning conflicts with earlier rights

- 1. A trade mark shall not be registered or, if registered, shall be liable to be declared invalid:
- (a) if it is identical with an earlier trade mark, and the goods or services for which the trade mark is applied for or is registered are identical with the goods or services for which the earlier trade mark is protected;
- (b) if because of its identity with, or similarity to, the earlier trade mark and the identity or similarity of the goods or services covered by the trade marks, there exists a likelihood of confusion on the part of the public; the likelihood of confusion includes the likelihood of association with the earlier trade mark.
- 2. 'Earlier trade marks' within the meaning of paragraph 1 means:
- (a) trade marks of the following kinds with a date of application for registration which is earlier than the date of application for registration of the trade mark, taking account, where appropriate, of the priorities claimed in respect of those trade marks;
 - (i) Community trade marks;
 - (ii) trade marks registered in the Member State or, in the case of Belgium, Luxembourg or the Netherlands, at the Benelux Office for Intellectual Property;

- (iii) trade marks registered under international arrangements which have effect in the Member State;
- (b) Community trade marks which validly claim seniority, in accordance with Council Regulation (EC) No 40/94 (¹) of 20 December 1993 on the Community trade mark, from a trade mark referred to in (a)(ii) and (iii), even when the latter trade mark has been surrendered or allowed to lapse;
- (c) applications for the trade marks referred to in points (a) and (b), subject to their registration;
- (d) trade marks which, on the date of application for registration of the trade mark, or, where appropriate, of the priority claimed in respect of the application for registration of the trade mark, are well known in a Member State, in the sense in which the words 'well known' are used in Article 6 bis of the Paris Convention.
- 3. A trade mark shall furthermore not be registered or, if registered, shall be liable to be declared invalid if it is identical with, or similar to, an earlier Community trade mark within the meaning of paragraph 2 and is to be, or has been, registered for goods or services which are not similar to those for which the earlier Community trade mark is registered, where the earlier Community trade mark has a reputation in the Community and where the use of the later trade mark without due cause would take unfair advantage of, or be detrimental to, the distinctive character or the repute of the earlier Community trade mark.
- 4. Any Member State may, in addition, provide that a trade mark shall not be registered or, if registered, shall be liable to be declared invalid where, and to the extent that:
- (a) the trade mark is identical with, or similar to, an earlier national trade mark within the meaning of paragraph 2 and is to be, or has been, registered for goods or services which are not similar to those for which the earlier trade mark is registered, where the earlier trade mark has a reputation in the Member State concerned and where the use of the later trade mark without due cause would take unfair advantage of, or be detrimental to, the distinctive character or the repute of the earlier trade mark;
- (b) rights to a non-registered trade mark or to another sign used in the course of trade were acquired prior to the date of application for registration of the subsequent trade mark, or the date of the priority claimed for the application for registration of the subsequent trade mark, and that nonregistered trade mark or other sign confers on its proprietor the right to prohibit the use of a subsequent trade mark;
- (c) the use of the trade mark may be prohibited by virtue of an earlier right other than the rights referred to in paragraph 2 and point (b) of this paragraph and in particular:
- (1) OJ L 11, 14.1.1994, p. 1.

- (i) a right to a name;
- (ii) a right of personal portrayal;
- (iii) a copyright;
- (iv) an industrial property right;
- (d) the trade mark is identical with, or similar to, an earlier collective trade mark conferring a right which expired within a period of a maximum of three years preceding application;
- (e) the trade mark is identical with, or similar to, an earlier guarantee or certification mark conferring a right which expired within a period preceding application the length of which is fixed by the Member State;
- (f) the trade mark is identical with, or similar to, an earlier trade mark which was registered for identical or similar goods or services and conferred on them a right which has expired for failure to renew within a period of a maximum of two years preceding application, unless the proprietor of the earlier trade mark gave his agreement for the registration of the later mark or did not use his trade mark;
- (g) the trade mark is liable to be confused with a mark which was in use abroad on the filing date of the application and which is still in use there, provided that at the date of the application the applicant was acting in bad faith.
- 5. The Member States may permit that in appropriate circumstances registration need not be refused or the trade mark need not be declared invalid where the proprietor of the earlier trade mark or other earlier right consents to the registration of the later trade mark.
- 6. Any Member State may provide that, by derogation from paragraphs 1 to 5, the grounds for refusal of registration or invalidity in force in that State prior to the date of the entry into force of the provisions necessary to comply with Directive 89/104/EEC, shall apply to trade marks for which application has been made prior to that date.

Rights conferred by a trade mark

- 1. The registered trade mark shall confer on the proprietor exclusive rights therein. The proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade:
- (a) any sign which is identical with the trade mark in relation to goods or services which are identical with those for which the trade mark is registered;

- (b) any sign where, because of its identity with, or similarity to, the trade mark and the identity or similarity of the goods or services covered by the trade mark and the sign, there exists a likelihood of confusion on the part of the public; the likelihood of confusion includes the likelihood of association between the sign and the trade mark.
- 2. Any Member State may also provide that the proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade any sign which is identical with, or similar to, the trade mark in relation to goods or services which are not similar to those for which the trade mark is registered, where the latter has a reputation in the Member State and where use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark.
- 3. The following, inter alia, may be prohibited under paragraphs 1 and 2:
- (a) affixing the sign to the goods or to the packaging thereof;
- (b) offering the goods, or putting them on the market or stocking them for these purposes under that sign, or offering or supplying services thereunder;
- (c) importing or exporting the goods under the sign;
- (d) using the sign on business papers and in advertising.
- 4. Where, under the law of the Member State, the use of a sign under the conditions referred to in paragraph 1(b) or paragraph 2 could not be prohibited before the date of entry into force of the provisions necessary to comply with Directive 89/104/EEC in the Member State concerned, the rights conferred by the trade mark may not be relied on to prevent the continued use of the sign.
- 5. Paragraphs 1 to 4 shall not affect provisions in any Member State relating to the protection against the use of a sign other than for the purposes of distinguishing goods or services, where use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark.

Limitation of the effects of a trade mark

- 1. The trade mark shall not entitle the proprietor to prohibit a third party from using, in the course of trade:
- (a) his own name or address;
- (b) indications concerning the kind, quality, quantity, intended purpose, value, geographical origin, the time of production

- of goods or of rendering of the service, or other characteristics of goods or services;
- (c) the trade mark where it is necessary to indicate the intended purpose of a product or service, in particular as accessories or spare parts;

provided he uses them in accordance with honest practices in industrial or commercial matters.

2. The trade mark shall not entitle the proprietor to prohibit a third party from using, in the course of trade, an earlier right which only applies in a particular locality if that right is recognised by the laws of the Member State in question and within the limits of the territory in which it is recognised.

Article 7

Exhaustion of the rights conferred by a trade mark

- 1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.
- 2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.

Article 8

Licensing

- 1. A trade mark may be licensed for some or all of the goods or services for which it is registered and for the whole or part of the Member State concerned. A licence may be exclusive or non-exclusive.
- 2. The proprietor of a trade mark may invoke the rights conferred by that trade mark against a licensee who contravenes any provision in his licensing contract with regard to:
- (a) its duration;
- (b) the form covered by the registration in which the trade mark may be used;
- (c) the scope of the goods or services for which the licence is granted;
- (d) the territory in which the trade mark may be affixed; or
- (e) the quality of the goods manufactured or of the services provided by the licensee.

Limitation in consequence of acquiescence

- 1. Where, in a Member State, the proprietor of an earlier trade mark as referred to in Article 4(2) has acquiesced, for a period of five successive years, in the use of a later trade mark registered in that Member State while being aware of such use, he shall no longer be entitled on the basis of the earlier trade mark either to apply for a declaration that the later trade mark is invalid or to oppose the use of the later trade mark in respect of the goods or services for which the later trade mark has been used, unless registration of the later trade mark was applied for in bad faith.
- 2. Any Member State may provide that paragraph 1 shall apply *mutatis mutandis* to the proprietor of an earlier trade mark referred to in Article 4(4)(a) or an other earlier right referred to in Article 4(4)(b) or (c).
- 3. In the cases referred to in paragraphs 1 and 2, the proprietor of a later registered trade mark shall not be entitled to oppose the use of the earlier right, even though that right may no longer be invoked against the later trade mark.

Article 10

Use of trade marks

1. If, within a period of five years following the date of the completion of the registration procedure, the proprietor has not put the trade mark to genuine use in the Member State in connection with the goods or services in respect of which it is registered, or if such use has been suspended during an uninterrupted period of five years, the trade mark shall be subject to the sanctions provided for in this Directive, unless there are proper reasons for non-use.

The following shall also constitute use within the meaning of the first subparagraph:

- (a) use of the trade mark in a form differing in elements which do not alter the distinctive character of the mark in the form in which it was registered;
- (b) affixing of the trade mark to goods or to the packaging thereof in the Member State concerned solely for export purposes.
- 2. Use of the trade mark with the consent of the proprietor or by any person who has authority to use a collective mark or a guarantee or certification mark shall be deemed to constitute use by the proprietor.
- 3. In relation to trade marks registered before the date of entry into force in the Member State concerned of the provisions necessary to comply with Directive 89/104/EEC:

- (a) where a provision in force prior to that date attached sanctions to non-use of a trade mark during an uninterrupted period, the relevant period of five years mentioned in the first subparagraph of paragraph 1 shall be deemed to have begun to run at the same time as any period of non-use which is already running at that date;
- (b) where there was no use provision in force prior to that date, the periods of five years mentioned in the first subparagraph of paragraph 1 shall be deemed to run from that date at the earliest

Article 11

Sanctions for non-use of a trade mark in legal or administrative proceedings

- 1. A trade mark may not be declared invalid on the ground that there is an earlier conflicting trade mark if the latter does not fulfil the requirements of use set out in Article 10(1) and (2), or in Article 10(3), as the case may be.
- 2. Any Member State may provide that registration of a trade mark may not be refused on the ground that there is an earlier conflicting trade mark if the latter does not fulfil the requirements of use set out in Article 10(1) and (2) or in Article 10(3), as the case may be.
- 3. Without prejudice to the application of Article 12, where a counter-claim for revocation is made, any Member State may provide that a trade mark may not be successfully invoked in infringement proceedings if it is established as a result of a plea that the trade mark could be revoked pursuant to Article 12(1).
- 4. If the earlier trade mark has been used in relation to part only of the goods or services for which it is registered, it shall, for purposes of applying paragraphs 1, 2 and 3, be deemed to be registered in respect only of that part of the goods or services.

Article 12

Grounds for revocation

1. A trade mark shall be liable to revocation if, within a continuous period of five years, it has not been put to genuine use in the Member State in connection with the goods or services in respect of which it is registered, and there are no proper reasons for non-use.

However, no person may claim that the proprietor's rights in a trade mark should be revoked where, during the interval between expiry of the five-year period and filing of the application for revocation, genuine use of the trade mark has been started or resumed.

The commencement or resumption of use within a period of three months preceding the filing of the application for revocation which began at the earliest on expiry of the continuous period of five years of non-use shall be disregarded where preparations for the commencement or resumption occur only after the proprietor becomes aware that the application for revocation may be filed.

- 2. Without prejudice to paragraph 1, a trade mark shall be liable to revocation if, after the date on which it was registered:
- (a) in consequence of acts or inactivity of the proprietor, it has become the common name in the trade for a product or service in respect of which it is registered;
- (b) in consequence of the use made of it by the proprietor of the trade mark or with his consent in respect of the goods or services for which it is registered, it is liable to mislead the public, particularly as to the nature, quality or geographical origin of those goods or services.

Article 13

Grounds for refusal or revocation or invalidity relating to only some of the goods or services

Where grounds for refusal of registration or for revocation or invalidity of a trade mark exist in respect of only some of the goods or services for which that trade mark has been applied for or registered, refusal of registration or revocation or invalidity shall cover those goods or services only.

Article 14

Establishment a posteriori of invalidity or revocation of a trade mark

Where the seniority of an earlier trade mark which has been surrendered or allowed to lapse is claimed for a Community trade mark, the invalidity or revocation of the earlier trade mark may be established *a posteriori*.

Article 15

Special provisions in respect of collective marks, guarantee marks and certification marks

1. Without prejudice to Article 4, Member States whose laws authorise the registration of collective marks or of guarantee or certification marks may provide that such marks shall not be registered, or shall be revoked or declared invalid, on grounds additional to those specified in Articles 3 and 12 where the function of those marks so requires.

2. By way of derogation from Article 3(1)(c), Member States may provide that signs or indications which may serve, in trade, to designate the geographical origin of the goods or services may constitute collective, guarantee or certification marks. Such a mark does not entitle the proprietor to prohibit a third party from using in the course of trade such signs or indications, provided he uses them in accordance with honest practices in industrial or commercial matters; in particular, such a mark may not be invoked against a third party who is entitled to use a geographical name.

Article 16

Communication

Member States shall communicate to the Commission the text of the main provisions of national law adopted in the field governed by this Directive.

Article 17

Repeal

Directive 89/104/EEC, as amended by the Decision listed in Annex I, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time limit for transposition into national law of that Directive, set out in Annex I, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex II.

Article 18

Entry into force

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

Article 19

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 22 October 2008.

For the European Parliament
The President
H.-G. PÖTTERING
For the Council
The President
J.-P. JOUYET

ANNEX I

PART A

Repealed Directive with its amendment

(referred to in Article 17)

Council Directive 89/104/EEC

(OJ L 40, 11.2.1989, p. 1)

Council Decision 92/10/EEC

(OJ L 6, 11.1.1992, p. 35)

PART B

Time limit for transposition into national law

(referred to in Article 17)

| Directive | Time limit for transposition |
|------------|------------------------------|
| 89/104/EEC | 31 December 1992 |

ANNEX II

Correlation table

| Directive 89/104/EEC | This Directive |
|---------------------------------------|---------------------------------------|
| Article 1 | Article 1 |
| Article 2 | Article 2 |
| Article 3(1)(a) to (d) | Article 3(1)(a) to (d) |
| Article 3(1)(e), introductory wording | Article 3(1)(e), introductory wording |
| Article 3(1)(e), first indent | Article 3(1)(e)(i) |
| Article 3(1)(e), second indent | Article 3(1)(e)(ii) |
| Article 3(1)(e), third indent | Article 3(1)(e)(iii) |
| Article 3(1)(f), (g) and (h) | Article 3(1)(f), (g) and (h) |
| Article 3(2), (3) and (4) | Article 3(2), (3) and (4) |
| Article 4 | Article 4 |
| Article 5 | Article 5 |
| Article 6 | Article 6 |
| Article 7 | Article 7 |
| Article 8 | Article 8 |
| Article 9 | Article 9 |
| Article 10(1) | Article 10(1), first subparagraph |
| Article 10(2) | Article 10(1), second subparagraph |
| Article 10(3) | Article 10(2) |
| Article 10(4) | Article 10(3) |
| Article 11 | Article 11 |
| Article 12(1), first sentence | Article 12(1), first subparagraph |
| Article 12(1), second sentence | Article 12(1), second subparagraph |
| Article 12(1), third sentence | Article 12(1), third subparagraph |
| Article 12(2) | Article 12(2) |
| Article 13 | Article 13 |
| Article 14 | Article 14 |
| Article 15 | Article 15 |
| Article 16(1) and (2) | _ |
| Article 16(3) | Article 16 |
| _ | Article 17 |
| _ | Article 18 |
| Article 17 | Article 19 |
| _ | Annex I |
| _ | Annex II |

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

CONFERENCE OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES of 29 October 2008

on the treatment of documents of EU civilian crisis management missions and military operations (2008/836)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN UNION,

Whereas:

- (1) Insofar as documents of European Union civilian crisis management missions and military operations are not held by an institution, they do not fall within the scope of Community law regarding historical archives and public access to documents.
- (2) Since such documents relate to the areas of activity of the European Union, it is appropriate that such documents be archived by the General Secretariat of the Council (GSC). These documents should henceforth be considered as documents held by the Council and should come within the scope of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (¹) and Council Regulation (EEC, Euratom) No 354/83 of 1 February 1983 concerning the opening to the public of the historical archives of the European Economic Community and the European Atomic Energy Community (²),

HAVE DECIDED AS FOLLOWS:

Article 1

1. For the purposes of applying Regulation (EC) No 1049/2001 and Regulation (EEC, Euratom) No 354/83,

(1) OJ L 145, 31.5.2001, p. 43.

(2) OJ L 43, 15.2.1983, p. 1.

documents of terminated, on-going and future civilian crisis management missions and military operations conducted under the auspices of the Council shall, upon termination of the missions and operations, be archived by the GSC and henceforth be considered as documents held by the Council.

- 2. The documents referred to in paragraph 1 shall not include documentation relating to staff issues, contracts with third parties and documentation pertaining thereto, or ephemeral documents.
- 3. The GSC shall ensure that documents classified by Member States or other authorities are protected in accordance with the Council's Security Regulations adopted by Council Decision 2001/264/EC (3).
- 4. The Member States shall assist the GSC in obtaining copies of the documents referred to in paragraph 1.
- 5. The documents referred to in paragraph 1 shall be held in a specific location of the Archives. The personnel handling these documents shall receive training on European Security and Defence Policy documents and on the handling of classified information in this context.

⁽³⁾ OJ L 101, 11.4.2001, p. 1.

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

Done at Brussels, 29 October 2008.

The President P. SELLAL

COMMISSION

COMMISSION DECISION

of 29 October 2008

authorising the placing on the market of products containing, consisting of, or produced from genetically modified LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document number C(2008) 6204)

(Only the German text is authentic)

(Text with EEA relevance)

(2008/837/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (¹), and in particular Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 3 March 2005, Bayer CropScience AG submitted to the competent authority of the Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from LLCotton25 (the application).
- (2) The application also covers the placing on the market of other products containing or consisting of LLCotton25 for the same uses as any other cotton with the exception of cultivation. Therefore, in accordance with the provisions of Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, it includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (²) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.

- (3) On 16 April 2007, the European Food Safety Authority (EFSA) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 and concluded that it is unlikely that the placing on the market of the products containing, consisting of, or produced from LLCotton25 as described in the application (the products) will have any adverse effects on human or animal health or the environment in the context of their intended uses (3). In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of that Regulation.
- (4) In particular, EFSA concluded that the comparative compositional analysis and agronomic analyses show that LLCottton25 is substantially equivalent to its nongenetically modified counterpart and, as a consequence, that no additional safety studies with laboratory animals (e.g. a 90-day toxicity study in rats) are needed.
- (5) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended use of the products. However, due to the physical characteristics of cotton seeds and methods of transportation, EFSA recommended that, within general surveillance, specific measures are introduced to actively monitor the occurrence of feral cotton plants in areas where seed spillage is likely to occur.
- (6) The monitoring plan submitted by the applicant has been modified to comply with this EFSA recommendation.
- (7) Taking into account those considerations, authorisation should be granted for the products.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

⁽³⁾ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_ 1178620785856.htm

- A unique identifier should be assigned to each GMO as provided for in Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (1).
- On the basis of the EFSA opinion, no specific labelling (9) requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for the foods, food ingredients and feed containing, consisting of, or produced from LLCotton25. However, in order to ensure the use of the products within the limits of the authorisation provided by this Decision, the labelling of feed containing or consisting of the GMO and other products than food and feed containing or consisting of the GMO for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.
- Similarly, the EFSA opinion does not justify the impo-(10)sition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.
- All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- Article 4(6) of Regulation (EC) No 1830/2003 of the Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (2), lays down labelling requirements for products consisting or containing GMOs.
- This decision is to be notified through the Biosafety Clearing House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (3).
- The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman; the Commission has

Council Decision 1999/468/EC (4), the Council being required to act within three months.

therefore submitted a proposal to the Council on

30 April 2008 in accordance with Article 5 of the

However, the Council has not acted within the required time limit; a Decision should now be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (Gossypium hirsutum) LLCotton25, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-GHØØ1-3, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from ACS-GHØØ1-3 cotton;
- (b) feed containing, consisting of, or produced from ACS-GHØØ1-3 cotton;
- (c) products other than food and feed containing or consisting of ACS-GHØØ1-3 cotton for the same uses as any other cotton with the exception of cultivation.

Article 3

Labelling

- For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
- The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of ACS-GHØØ1-3 cotton referred to in Article 2(b) and (c).

⁽¹⁾ OJ L 10, 16.1.2004, p. 5.

⁽²⁾ OJ L 268, 18.10.2003, p. 24. (3) OJ L 287, 5.11.2003, p. 1.

⁽⁴⁾ OJ L 184, 17.7.1999, p 23.

Monitoring for environmental effects

- 1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in the point (h) of the Annex, is put in place and implemented.
- 2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring activities.

Article 5

Community register

The information in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

Article 6

Authorisation holder

The authorisation holder shall be Bayer CropScience AG.

Article 7

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 8

Addressee

This Decision is addressed to Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein, Germany.

Done at Brussels, 29 October 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Bayer CropScience AG

Address: Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein, Germany.

(b) Designation and specification of the products:

- 1. foods and food ingredients containing, consisting of, or produced from ACS-GHØØ1-3 cotton;
- 2. feed containing, consisting of, or produced from ACS-GHØØ1-3 cotton;
- 3. products other than food and feed containing or consisting of ACS-GHØØ1-3 cotton for the same uses as any other cotton with the exception of cultivation.

The genetically modified ACS-GHØØ1-3 cotton, as described in the application, expresses the PAT protein which confers tolerance to the herbicide glufosinate-ammonium.

(c) Labelling:

- 1. For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
- 2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of ACS-GHØØ1-3 cotton referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection:

- event specific real-time PCR-based method for the quantification of ACS-GHØØ1-3 cotton,
- validated on seeds by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.it/statusofdoss.htm
- reference material: AOCS 0306-A and AOCS 0306-E accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm/bayer_cotton.cfm

(e) Unique identifier:

ACS-GHØØ1-3.

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Biosafety Clearing House, Record ID: see [to be completed when notified].

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: plan published on the Internet.]

(i) Post-market monitoring requirements for the use of the food for human consumption:

Not required.

Note: Links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION DECISION

of 3 November 2008

concerning preventive vaccination against low pathogenic avian influenza in mallard ducks in Portugal and certain measures restricting the movements of such poultry and their products

(notified under document number C(2008) 6348)

(Only the Portuguese text is authentic)

(2008/838/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (¹), and in particular Article 57(2) thereof,

Whereas:

- (1) Directive 2005/94/EC sets out certain preventive measures relating to the surveillance and the early detection of avian influenza and increasing the level of the competent authorities' and the farming community's awareness of, and preparation for, the risks of that disease.
- (2) Since September 2007, outbreaks of low pathogenic avian influenza have occurred in certain poultry holdings in the central-western part of Portugal, in particular in holdings that keep poultry intended for restocking supplies of game.
- (3) Portugal has taken measures in accordance with Directive 2005/94/EC to control the spread of that disease.
- (4) A risk assessment carried out by Portugal identified that holdings keeping mallard ducks (Anas platyrhynchos) intended for re-stocking supplies of game (mallard ducks) could pose a significant and immediate threat of spreading avian influenza within Portugal or into other Member States. Portugal decided therefore to introduce emergency vaccination in order to contain the outbreak.
- (5) Commission Decision 2008/285/EC (²) approved the emergency vaccination plan submitted by Portugal. That Decision also provided for certain measures to be applied in a holding where vaccinated mallard ducks are kept and in unvaccinated poultry holdings, including movement restrictions on vaccinated mallard ducks, their hatching eggs and mallard ducks hatched from such eggs in accordance with the approved vaccination plan.
- (1) OJ L 10, 14.1.2006, p. 16.
- (2) OJ L 92, 3.4.2008, p. 37.

- (6) The implementation of the emergency vaccination plan applied by Portugal has been completed by 31 July 2008.
- (7) In accordance with Article 8 of Decision 2008/285/EC, Portugal has submitted a report on the implementation of the emergency vaccination plan and has reported to the Standing Committee on the Food Chain and Animal Health.
- (8) On the basis of the information provided by Portugal, it appears that the outbreak has been successfully contained.
- (9) Based on a further risk assessment, Portugal deems that on the holding the high value mallard breeding ducks are still exposed to the potential risk of avian influenza infection, in particular by possible indirect contact with wild birds. Portugal has therefore decided to continue vaccination against avian influenza as a long-term measure by implementing a preventive vaccination plan on the holding at risk in the region of Lisboa e Vale do Tejo, Ribatejo Norte, Vila Nova da Barquinha that keeps such mallard ducks.
- (10) Portugal has by letter dated 10 September 2008 submitted a preventive vaccination plan to the Commission for approval.
- (11) According to that preventive vaccination plan, Portugal intends to introduce preventive vaccination which is to be applied until 31 July 2009.
- (12) In its scientific opinions on the use of vaccination to control avian influenza issued by the European Food Safety Authority in 2005 (3), 2007 (4) and 2008 (5), the Animal Health and Welfare Panel stated that emergency and preventive vaccination against avian influenza is a valuable tool to complement the control measures for that disease.

⁽³⁾ The EFSA Journal (2005) 266, 1-21, Scientific Opinion on Animal health and welfare aspects of avian influenza.

⁽⁴⁾ The EFSA Journal (2007) 489, Scientific Opinion on Vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds.

⁽⁵⁾ The EFSA Journal (2008) 715, 1-161, Scientific Opinion on Animal health and welfare aspects of avian influenza and the risks of its introduction into the EU poultry holdings.

- (13) In addition, the Commission has examined the preventive vaccination plan submitted by Portugal, and is satisfied that it conforms with relevant Community legislation. In view of the epidemiological situation as regards low pathogenic avian influenza in Portugal, the type of holding to be vaccinated and the limited scope of the vaccination plan, it is appropriate to approve that preventive vaccination plan. The implementation of that preventive vaccination plan will also provide with further practical experience and knowledge on the efficacy of vaccine in mallard ducks.
- (14) For the purposes of the preventive vaccination plan to be carried out by Portugal, only vaccines authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (¹) or Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (²) should be used.
- (15) In addition, surveillance and laboratory testing in the holding keeping the vaccinated mallard ducks and in unvaccinated poultry holdings should be carried out as set out in the preventive vaccination plan.
- (16) It is also appropriate to introduce certain restrictions on the movement of vaccinated mallard ducks, their hatching eggs and mallard ducks derived from vaccinated poultry in accordance with the preventive vaccination plan. Due to the small number of mallard ducks present on the holding where preventive vaccination is to be carried out, as well as for reasons of traceability and logistics, vaccinated birds should not be moved from that holding.
- (17) In relation to trade in poultry intended for restocking supplies of game, additional measures have been taken by Portugal pursuant to Commission Decision 2006/605/EC of 6 September 2006 on certain protection measures in relation to intra-Community trade in poultry intended for restocking of wild game supplies (3).
- (18) In order to reduce the economic impact on the holding concerned, certain derogations from movement restrictions for mallard ducks derived from vaccinated mallard ducks should be provided for, since such movements do not pose a specific risk for spread of disease and provided that official surveillance is carried out and that the specific animal health requirements for intra-Community trade are complied with.
- (1) OJ L 311, 28.11.2001, p. 1.
- (2) OJ L 136, 30.4.2004, p. 1.
- (3) OJ L 246, 8.9.2006, p. 12.

- (19) The preventive vaccination plan should be approved so that it can be implemented until 31 July 2009.
- (20) Decision 2008/285/EC should be repealed as it has become obsolete after 31 July 2008.
- (21) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

- 1. This Decision lays down certain measures to be applied in Portugal where preventive vaccination of mallard ducks (*Anas platyrhynchos*) intended for re-stocking supplies of game (mallard ducks) is carried out in a holding, which is exposed to the risk of avian influenza. Those measures include certain restrictions on the movement within and dispatch from Portugal of the vaccinated mallard ducks, their hatching eggs and mallard ducks derived thereof.
- 2. This Decision shall apply without prejudice to the protection measures to be taken by Portugal in accordance with Directive 2005/94/EC and Decision 2006/605/EC.

Article 2

Approval of the preventive vaccination plan

- 1. The plan for preventive vaccination against low pathogenic avian influenza in Portugal, as submitted by Portugal to the Commission on 10 September 2008, to be implemented on a holding in the region of Lisboa e Vale do Tejo, Ribatejo Norte, Vila Nova da Barquinha until 31 July 2009 (the preventive vaccination plan) is approved.
- 2. The Commission shall publish the preventive vaccination plan.

Article 3

Conditions for implementing the preventive vaccination plan

- 1. Portugal shall ensure that the mallard ducks are vaccinated in accordance with the preventive vaccination plan with a bivalent inactivated heterologous vaccine containing both avian influenza subtypes H5 and H7 authorised by that Member State in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
- 2. Portugal shall ensure that surveillance and laboratory testing of the holding keeping the vaccinated mallard ducks and in unvaccinated poultry holdings, as set out in the preventive vaccination plan, is carried out.

3. Portugal shall ensure that the preventive vaccination plan is implemented efficiently.

Article 4

Marking and restrictions on the movement and dispatch and disposal of vaccinated mallard ducks

The competent authority shall ensure that vaccinated mallard ducks on the holding referred to in Article 2(1) are:

- (a) marked individually;
- (b) not moved to other poultry holdings within Portugal or dispatched to other Member States.

After their reproductive period, such ducks shall be killed humanely on the holding referred to in Article 2(1) and their carcases safely disposed of.

Article 5

Restrictions on the movement and dispatch of hatching eggs originating from the holding referred to in Article 2(1)

The competent authority shall ensure that hatching eggs originating from mallard ducks on the holding referred to in Article 2(1) may only be moved to a hatchery within Portugal and not dispatched to other Member States.

Article 6

Restrictions on the movement and dispatch of mallard ducks derived from vaccinated mallard ducks

- 1. The competent authority shall ensure that mallard ducks derived from vaccinated mallard ducks may only be moved after hatching to a holding located in a surrounding area established in Portugal in relation to the holding referred to in Article 2(1) as set out in the preventive vaccination plan.
- 2. By way of derogation from paragraph 1 and provided that the mallard ducks derived from vaccinated mallard ducks are more than four month old, they may be:
- (a) released into the wild in Portugal; or
- (b) dispatched to other Member States provided that:
 - (i) the results of the surveillance and laboratory tests as set out in the preventive vaccination plan, are favourable;
 and

(ii) the conditions for dispatch of poultry for re-stocking supplies of wild game laid down in Decision 2006/605/EC are met.

Article 7

Health certification for intra-Community trade in mallard ducks derived from vaccinated mallard ducks

Portugal shall ensure that health certificates for intra-Community trade in poultry intended for re-stocking supplies of game referred to in Article 6(2)(b) include the following sentence:

The animal health conditions of this consignment are in accordance with Decision 2008/838/EC (*).

(*) OJ L 299, 8.11.2008, p. 40.'.

Article 8

Reports

Portugal shall submit to the Commission a report on the implementation of the preventive vaccination plan within one month from the date of application of this Decision and give quarterly reports at the Standing Committee on the Food Chain and Animal Health thereafter.

Article 9

Repeal

Decision 2008/285/EC shall be repealed.

Article 10

Applicability

This Decision shall apply until 31 July 2009.

Article 11

Addressees

This Decision is addressed to the Portuguese Republic.

Done at Brussels, 3 November 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

III

(Acts adopted under the EU Treaty)

ACTS ADOPTED UNDER TITLE V OF THE EU TREATY

COUNCIL DECISION 2008/839/JHA

of 24 October 2008

on migration from the Schengen Information System (SIS 1+) to the second generation Schengen Information System (SIS II)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 30(1)(a) and (b), 31(1)(a) and (b) and 34(2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Whereas:

- (1) The Schengen Information System (SIS), set up pursuant to the provisions of Title IV of the Convention of 19 June 1990 implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders (2) (the Schengen Convention), and the further development thereof, SIS 1+, constitute essential tools for the application of the provisions of the Schengen acquis as integrated into the framework of the European Union.
- (2)The development of the second generation Schengen Information System (SIS II) was to the Commission pursuant to Council Regulation (EC) No 2424/2001 (3) and Council Decision 2001/886/JHA (4). instruments expire on 31 December 2008. This Decision should therefore supplement them until a date

to be fixed by the Council acting in accordance with Council Decision 2007/533/JHA of 12 June 2007 on the establishment, operation and use of the second generation Schengen Information System (SIS II) (5).

- SIS II was established by Regulation (EC) No 1987/2006 of the European Parliament and of the Council of 20 December 2006 on the establishment, operation and use of the second generation Schengen Information System (SIS II) (6) and by Council Decision 2007/533/JHA. This Decision should be without prejudice to the provisions of those acts.
- Certain tests of SIS II are provided for in Council Regulation (EC) No 189/2008 (7) and in Council Decision 2008/173/EC (8).
- The development of SIS II should be continued and should be finalised in the framework of the SIS II global schedule endorsed by the Council on 6 June 2008.
- A comprehensive test of SIS II should be conducted in full cooperation between the Member States and the Commission, in accordance with the provisions of this Decision. As soon as possible after its completion, the test should be validated as provided for by Regulation (EC) No 1987/2006 and Decision 2007/533/JHA.
- Member States should perform a test on the exchange of supplementary information.

⁽¹⁾ Opinion of 24 September 2008 (not yet published in the Official Journal).

⁽²⁾ OJ L 239, 22.9.2000, p. 19.

⁽³⁾ OJ L 328, 13.12.2001, p. 4.

⁽⁴⁾ OJ L 328, 13.12.2001, p. 1.

⁽⁵⁾ OJ L 205, 7.8.2007, p. 63.

⁽⁶⁾ OJ L 381, 28.12.2006, p. 4.

⁽⁷⁾ OJ L 57, 1.3.2008, p. 1. (8) OJ L 57, 1.3.2008, p. 14.

- As regards SIS 1+, the Schengen Convention provides for a technical support function (C.SIS). As regards SIS II, Regulation (EC) No 1987/2006 and Decision 2007/533/JHA provide for a Central SIS II composed of a technical support function and a uniform national interface (NI-SIS). The technical support function of Central SIS II should be located in Strasbourg (France) and a back-up in St. Johann im Pongau (Austria).
- In order to better manage the potential difficulties brought about by the migration from SIS 1+ to SIS II an interim migration architecture for the Schengen Information System should be established and tested. The interim migration architecture should have no impact on the operational availability of SIS 1+. A converter should be provided by the Commission.
- The Member State issuing an alert should be responsible for ensuring that the data entered into the Schengen Information System is accurate, up-to-date and lawful.
- The Commission should remain responsible for Central SIS II and its communication infrastructure. This responsibility includes the maintenance and continuation of the development of SIS II and its communication infrastructure, including at all times the correction of errors. The Commission should provide coordination and support for the joint activities. The Commission should provide, in particular, the necessary technical and operational support to the Member States at Central SIS II level including the availability of a helpdesk.
- The Member States are and should remain responsible (12)for the development and maintenance of their national systems (N.SIS II).
- (13)France should remain responsible for the technical support function of SIS 1+, as expressly provided for in the Schengen Convention.
- Representatives of the Member States participating in SIS 1+ should coordinate their actions within the framework of the Council. It is necessary to set out a framework for that organisational action.
- The Commission should be empowered to contract out to third parties, including national public bodies, tasks conferred upon it by this Decision and tasks relating to the implementation of the budget, in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (1).

- Any such contract should respect the rules of data protection and data security and take into account the role of the relevant data protection authorities applicable to the SIS, in particular the provisions of the Schengen Convention and of this Decision.
- Regulation (EC) No 45/2001 of the European Parliament (16)and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (2) applies to the processing of personal data by the Commission.
- The European Data Protection Supervisor, appointed (17)pursuant to Decision 2004/55/EC of the European Parliament and of the Council of 22 December 2003 appointing the independent supervisory body provided for in Article 286 of the EC Treaty (3), is competent to monitor the activities of the Community institutions and bodies in relation to the processing of personal data. The Schengen Convention contains specific provisions on the protection and security of personal data.
- Since the objectives of setting up the interim migration (18)architecture and migrating the data from SIS 1+ to SIS II, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the action, be better achieved at the level of the Union, it is considered that the adoption of the present measure is in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty Establishing the European Community and referred to in Article 2 of the Treaty on European Union. In accordance with the principle of proportionality, this Decision does not go beyond what is necessary to achieve those objectives.
- (19)This Decision respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.
- The Schengen Convention should be amended to allow the integration of SIS 1+ into the interim migration architecture.
- The United Kingdom is taking part in this Decision, in (21)accordance with Article 5 of the Protocol integrating the Schengen acquis into the framework of the European Union, annexed to the Treaty on European Union and to the Treaty Establishing the European Community, and Article 8(2) of 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 (4).

⁽²⁾ OJ L 8, 12.1.2001, p. 1.

⁽³⁾ OJ L 12, 17.1.2004, p. 47. (4) OJ L 131, 1.6.2000, p. 43.

⁽¹⁾ OJ L 248, 16.9.2002, p. 1.

- Ireland is taking part in this Decision in accordance with Article 5 of the Protocol integrating the Schengen acquis into the framework of the European Union annexed to the Treaty on European Union and to the Treaty Establishing the European Community, and Article 6(2) of 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 (1).
- This Decision is without prejudice to the arrangements for the United Kingdom's and Ireland's partial participation in the Schengen acquis as determined by Council Decisions 2000/365/EC and 2002/192/EC respectively.
- As regards Iceland and Norway, this Decision constitutes a development of provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (2), which fall within the area referred to in Article 1, point G of Council Decision 1999/437/EC (3) on certain arrangements for the application of that Agreement.
- As regards Switzerland, this Decision constitutes a development of provisions of the Schengen acquis within the meaning of the Agreement concluded between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (4), which fall within the area referred to in Article 1, point G of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/149/JHA (5) on the conclusion of that Agreement on behalf of the European Union.
- As regards Liechtenstein, this Decision constitutes a (26)development of provisions of the Schengen acquis within the meaning of the Protocol signed between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement concluded between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, which fall within the area referred to in Article 1, point G of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2008/262/EC of 28 February 2008 on the signature, on behalf of the European Union, and on the provisional application of certain provisions of that Protocol (6),

(1) OJ L 64, 7.3.2002, p. 20.

(6) OJ L 83, 26.3.2008, p. 5.

HAS ADOPTED THIS DECISION:

Article 1

General purpose

- 1. The Schengen Information System (SIS 1+) set up pursuant to the provisions of Title IV of the Schengen Convention, shall be replaced by a new system, the Schengen Information System II (SIS II), the establishment, operation and use of which is regulated by Decision 2007/533/JHA.
- In accordance with the procedures and the division of tasks set out in this Decision, SIS II shall be developed by the Commission and the Member States as a single integrated system and shall be prepared for operations.

Article 2

Definitions

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

- (a) 'Central SIS II' means the technical support function of SIS II containing a database, the 'SIS II database', and a uniform national interface (NI-SIS);
- (b) 'C.SIS' means the technical support function of SIS 1+, containing the reference database for SIS 1+ and the uniform national interface (N.COM);
- (c) 'N.SIS' means the national system of SIS 1+, consisting of the national data systems which communicate with C.SIS;
- (d) 'N.SIS II' means the national system of SIS II, consisting of the national data systems which communicate with Central SIS II:
- (e) 'converter' means a technical tool to allow consistent and reliable communication between C.SIS and Central SIS II, ensuring the functionalities provided for in Article 10(3);
- (f) 'comprehensive test' means the test referred to in Article 71(3)(c) of Decision 2007/533/JHA;
- (g) 'test on supplementary information' means functional tests between the SIRENE Bureaux.

Article 3

Subject matter and scope

This Decision defines the tasks and responsibilities of the Commission and the Member States participating in SIS 1+ with respect to the following tasks:

⁽²⁾ OJ L 176, 10.7.1999, p. 36. (3) OJ L 176, 10.7.1999, p. 31.

⁽⁴⁾ OJ L 53, 27.2.2008, p. 52. (5) OJ L 53, 27.2.2008, p. 50.

- (a) the maintenance and continuation of the development of SIS II;
- (b) a comprehensive test of SIS II;
- (c) a test on supplementary information;
- (d) the continuation of the development and testing of a converter:
- (e) the establishment and testing of a provisional migration architecture;
- (f) the migration from SIS 1+ to SIS II.

Technical components of the migration architecture

In order to ensure the migration from SIS 1+ to SIS II, the following components are necessary:

- (a) the C.SIS and the connection to the converter;
- (b) the communication infrastructure for SIS 1+ allowing the C.SIS to communicate with the N.SIS;
- (c) the N.SIS;
- (d) Central SIS II, NI-SIS and the communication infrastructure for SIS II allowing the Central SIS II to communicate with N.SIS II and the converter;
- (e) the N.SIS II;
- (f) the converter.

Article 5

Main responsibilities in the development of SIS II

- 1. The Commission shall continue to develop Central SIS II, the communication infrastructure and the converter.
- 2. France shall make available and operate C.SIS in accordance with the provisions of the Schengen Convention.
- 3. The Member States shall continue to develop N.SIS II.
- 4. The Member States participating in SIS 1+ shall maintain N.SIS in accordance with the provisions of the Schengen Convention.
- 5. The Member States participating in SIS 1+ shall make available and operate the communication infrastructure for SIS 1+.
- 6. The Commission shall coordinate the activities and provide the necessary support for the implementation of the tasks and responsibilities referred to in paragraphs 1 to 3.

Article 6

Continuing development

The measures necessary to continue the development of SIS II as referred to in Article 5(1), in particular measures necessary for the corrections of errors, shall be adopted in accordance with the procedure defined in Article 17(2).

The measures necessary to continue the development of SIS II as referred to in Article 5(3), in so far as it concerns the uniform national interface ensuring the compatibility of N.SIS II with Central SIS II, shall be adopted in accordance with the procedure defined in Article 17(2).

Article 7

Main activities

- 1. The Commission together with the Member States participating in SIS 1+ shall conduct a comprehensive test.
- 2. An interim SIS migration architecture shall be set up and a test of that architecture shall be performed by the Commission together with the Member States participating in SIS 1+.
- 3. The Commission and the Member States participating in SIS 1+ shall perform the migration from SIS 1+ to SIS II.
- 4. The Member States participating in SIS 1+ shall perform a test on the exchange of supplementary information.
- 5. The Commission shall provide the necessary support at Central SIS II level for the activities in paragraphs 1 to 4.
- 6. The activities in paragraphs 1 to 3 shall be coordinated by the Commission and the Member States participating in SIS 1+ acting within the Council.

Article 8

Comprehensive test

- 1. The comprehensive test shall not start before the Commission has declared that it considers that the level of success of the tests referred to in Article 1 of Decision 2008/173/EC is sufficient to begin such a test.
- 2. A comprehensive test aiming at confirming, in particular, the completion by the Commission and the Member States participating in SIS 1+ of the necessary technical arrangements to process SIS II data and the demonstration that the level of performance of SIS II is at least equivalent to that achieved with SIS 1+ shall be performed.
- 3. The comprehensive test shall be executed by the Member States participating in SIS 1+ for the N.SIS II and by the Commission for the Central SIS II.

- 4. The comprehensive test shall follow a detailed schedule defined by Member States participating in SIS 1+ acting within the Council in cooperation with the Commission.
- 5. The comprehensive test shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council in cooperation with the Commission
- 6. The Commission and the Member States participating in SIS 1+ acting within the Council shall define the criteria for determining whether the necessary technical arrangements to process SIS II data are completed and the level of performance of SIS II is at least equivalent to that achieved with SIS 1+.
- 7. The test results shall be analysed using the criteria mentioned in paragraph 6, by the Member States participating in SIS 1+ acting within the Council and the Commission. The test results shall be validated in accordance with Article 71(3)(c) of Decision 2007/533/JHA.
- 8. Member States not participating in SIS 1+ may participate in the comprehensive test. Their results shall not affect the overall validation of the test.

Test on supplementary information

- 1. The Member States participating in SIS 1+ shall conduct functional SIRENE tests.
- 2. The Commission shall make available Central SIS II and its communication infrastructure during the execution of the test on supplementary information.
- 3. The test on supplementary information shall follow a detailed schedule defined by Member States participating in SIS 1 + acting within the Council.
- 4. The test on supplementary information shall be based on the technical specifications defined by the Member States participating in SIS 1+ acting within the Council.
- 5. The test results shall be analysed by the Member States participating in SIS 1+ acting within the Council.
- 6. Member States not participating in SIS 1+ may participate in the test on supplementary information. Their results shall not affect the overall validation of the test.

Article 10

Interim migration architecture

1. An interim SIS migration architecture shall be set up. The converter connects Central SIS II and C.SIS for a transitional

period. The N.SIS are connected to C.SIS, the N.SIS II to Central SIS II.

- 2. The Commission shall provide a converter, the Central SIS II and its communication infrastructure as part of the interim SIS migration architecture.
- 3. The converter shall convert data in two directions between the C.SIS and Central SIS II and keep C.SIS and Central SIS II synchronised.
- 4. The Commission shall test the communication between Central SIS II and the converter.
- 5. France shall test the communication between C.SIS and the converter.
- 6. The Commission and France shall test the communication between Central SIS II and C.SIS via the converter.
- 7. France, together with the Commission, shall connect C.SIS via the converter to Central SIS II.
- 8. The Commission, together with France and the other Member States participating in SIS 1+, shall test the interim SIS migration architecture as a whole in accordance with a test plan provided by the Commission.
- 9. France shall make available data for test purpose, if necessary.

Article 11

Migration from SIS 1+ to SIS II

- 1. For the migration from C.SIS to Central SIS II, France shall make available the SIS 1+ database and the Commission shall introduce the SIS 1+ database into Central SIS II.
- 2. The Member States participating in SIS 1+ shall migrate from N.SIS to N.SIS II using the interim migration architecture, with the support of France and of the Commission, by 30 September 2009 at the latest. If necessary, this date may be changed in accordance with the procedure defined in Article 17(2).
- 3. The migration of the national system from SIS 1+ to SIS II consists of the data loading of N.SIS II, when that N.SIS II is to contain a data file, the national copy, containing a complete or partial copy of the SIS II database, followed by a switchover from N.SIS to N.SIS II for each Member State. The migration shall follow a detailed schedule provided by the Commission and the Member States participating in SIS 1+ acting within the Council.

- 4. The Commission shall assist in coordination and support of the common activities during the migration.
- 5. The switchover foreseen in the migration process shall be carried out after the validation mentioned in Article 8(7).

Substantive legal framework

During the migration, the provisions of Title IV of the Schengen Convention shall continue to apply to the Schengen Information System.

Article 13

Cooperation

- 1. The Member States and the Commission shall cooperate for the execution of all the activities covered by this Decision in accordance with their respective responsibilities.
- 2. The Commission shall in particular provide the necessary support at Central SIS II level for the testing and migration of N.SIS II.
- 3. Member States shall in particular provide the necessary support at N.SIS II level for the testing of the interim migration infrastructure.

Article 14

Keeping of records in Central SIS II

- 1. Without prejudice to the relevant provisions of Title IV of the Schengen Convention, the Commission shall ensure that every access to and all exchanges of personal data within Central SIS II are recorded for the purposes of checking whether or not the search is lawful, monitoring the lawfulness of data processing and ensuring the proper functioning of Central SIS II and of national systems, data integrity and security.
- 2. The records shall show, in particular, the date and time of the data transmitted, the data used to perform searches, the reference to the data transmitted and the name of the competent authority responsible for processing the data.
- 3. The records may only be used for the purposes referred to in paragraph 1 and shall be deleted at the earliest one year, and at the latest three years after their creation.
- 4. Records may be kept longer if they are required for monitoring procedures that are already underway.
- 5. The competent authorities in charge of checking whether or not a search is lawful, monitoring the lawfulness of data processing, self-monitoring and ensuring the proper functioning of Central SIS II, data integrity and security, shall have access,

within the limits of their competence and at their request, to those records for the purpose of fulfilling their tasks.

Article 15

Costs

- 1. The costs arising from migration, the comprehensive test, the test on supplementary information, maintenance and development measures at Central SIS II level or concerning the communication infrastructure shall be borne by the general budget of the European Union.
- 2. The costs arising from migration, testing, maintenance and development of the national systems shall be borne by each Member State concerned.
- 3. The costs arising from activities at SIS 1+ level, including supplementary activities of France, acting on behalf of the Member States participating in SIS 1+, shall be borne in accordance with the provisions of Article 119 of the Schengen Convention.

Article 16

Amendment of the provisions of the Schengen Convention

The provisions of the Schengen Convention are hereby amended as follows:

1. the following Article shall be inserted:

'Article 92A

- 1. As from the entry into force of Council Regulation (EC) No 1104/2008 (*) and Council Decision 2008/839/JHA (**) and relying on the definitions in Article 2 of that Regulation, the technical architecture of the Schengen Information System may be supplemented by:
- (a) an additional central system composed of:
 - technical support function (Central SIS II), located in France and backup Central SIS II located in Austria, containing the SIS II database and a uniform national interface (NI-SIS),
 - a technical connection between the C.SIS and the Central SIS II via the converter allowing the conversion and synchronisation of data between the C.SIS and the Central SIS II;
- (b) a national system (N.SIS II), consisting of the national data systems, which communicates with the Central SIS II;
- (c) an infrastructure for communication between Central SIS II and the N.SIS II connected to the NI-SIS.

- 2. The N.SIS II may replace the national section referred to in Article 92 of this Convention, in which case the Member States need not hold a national data file.
- 3. The central SIS II database shall be available for the purpose of carrying out automated searches in the territory of each Member State.
- 4. In case any of the Member States replace their national section by N.SIS II, the compulsory functions of the technical support function towards that national section as mentioned in Article 92(2) and (3) become compulsory functions towards Central SIS II, without prejudice to the obligations referred to in Council Decision 2008/839/JHA and in Articles 5(1), 10(1), (2) and (3) of Council Regulation (EC) No 1104/2008.
- 5. Central SIS II shall provide the services necessary for the entry and processing of SIS data, the on-line update of N.SIS II national copies, the synchronisation of and consistency between N.SIS II national copies and the Central SIS II database and provide operations for initialisation and restoration of N.SIS II national copies.
- 6. France, responsible for the technical support function, the other Member States and the Commission shall cooperate to ensure that a search in the data files of N.SIS II or in the SIS II database produces a result equivalent to that of a search in the data file of the national sections referred to in Article 92(2).
- (*) OJ L 299, 8.11.2008, p. 1. (**) OJ L 299, 8.11.2008, p. 43.';
- 2. in Article 119 first paragraph, the first sentence shall be replaced by the following:

The costs of installing and operating the technical support function referred to in Article 92(3), including the cost of lines connecting the national sections of the Schengen Information System to the technical support function, and of activities performed in conjunction with tasks conferred upon France in application of Council Decision 2008/839/JHA and of Council Regulation (EC) No 1104/2008 shall be borne jointly by the Member States.';

3. in Article 119, the second paragraph shall be replaced by the following:

The costs of installing and operating the national section of the Schengen Information System and of tasks conferred upon national systems under Council Decision 2008/839/JHA and Council Regulation (EC) No 1104/2008 shall be borne by each Member State individually.'

Article 17

Committee

- 1. The Commission shall be assisted by the Committee established by Article 67(1) of Decision 2007/533/JHA.
- 2. Where reference is made to this paragraph, the procedure set out in Article 67 of Decision 2007/533/JHA shall apply.

Article 18

Reporting

The Commission shall submit by the end of every six month period, and for the first time by the end of the first six month period of 2009, a progress report to the European Parliament and the Council concerning the development of SIS II and the migration from SIS 1+ to SIS II.

Article 19

Entry into force and applicability

This Decision shall enter into force on the third day following its publication in the *Official Journal of the European Union*. It shall expire on a date to be fixed by the Council, acting in accordance with Article 71(2) of Decision 2007/533/JHA, and in any case no later than on 30 June 2010.

Done at Luxembourg, 24 October 2008.

For the Council The President M. ALLIOT-MARIE

CORRIGENDA

Corrigendum to Commission Regulation (EC) No 1379/2007 of 26 November 2007 amending Annexes IA, IB, VII and VIII of Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste, for the purposes of taking into account of technical progress and changes agreed under the Basel Convention

(Official Journal of the European Union L 309 of 27 November 2007)

On page 9, Annex I (Annex IA — Notification document for transboundary movements/shipments of waste) and on page 14, Annex II (Annex IB — Movement document for transboundary movements/shipments of waste), the model forms are replaced, respectively, by the following models:

'Notification document for transboundary movements/shipments of waste

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| 1. Exporter — notifier | Registratio | n No: | 3. Notificatio | n No: | | | | |
| Name: | | | Notification of | concerning | | | | |
| Address: | | | A. (i) Individ | ual shipment: | | (ii) Mu | Itiple shipments: | |
| | | | B. (i) Dispos | al (¹): | | (ii) Re | covery: | |
| Contact person: | | | C. Pre-conse | ented recovery fa | acility (2) (3) | | Yes □ | No □ |
| Tel.: | Fax: | | 4 Total inter | nded number o | f shinments: | | | |
| E-mail: | | | 41 Total littor | idod ildilibor o | ompinono. | | | |
| | | | 5. Total inter | nded quantity (4 |): | | | |
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| Contact person: | Favo | | First departure | ə: | | La | ast departure: | |
| Tel.: | Fax: | | 7. Packaging | type(s) (⁵): | | | | |
| E-mail: | | | Special hand | lling requireme | nts (⁶): | | Yes □ | No □ |
| | | | 11. Disposal/ | recovery opera | tion(s) (2) | | | |
| 8. Intended carrier(s) | Registratio | a No: | D-code/R-cod | | • | | | |
| Name (⁷): | Hegistiatio | TNO. | Technology e | | | | | |
| Address: | | | Technology e | mployed (*). | | | | |
| Address. | | | | | | | | |
| Contact person: | | | Reason for ex | (port (') (°): | | | | |
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| ' ',' | (1) (7) (8) Deviletorities | - NI | 1 | | | | | |
| 9. Waste generator(s) — producer(s) | (1) (7) (8) Registration | 1 No: | | | | | | |
| Name: | | | 13. Physical | characteristics | (⁵): | | | |
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| Site and process of generation (6) | | | (ii) OECD co | ode (if different t | rom (i)): | | | |
| Site and process of generation (*) | | | (iii) EC list o | f wastes: | | | | |
| 10. Disposal facility (²): □ | or recovery facility (| ²): □ | (iv) National | code in country | of export: | | | |
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List of abbreviations and codes used in the notification document

DISPOSAL OPERATIONS (block 11)

- D1 Deposit into or onto land (e.g. landfill, etc.)
- D2 Land treatment (e.g., biodegradation of liquid or sludgy discards in soils, etc.)
- D3 Deep injection (e.g. injection of pumpable discards into wells, salt domes or naturally occurring repositories, etc.)
- D4 Surface impoundment (e.g. placement of liquid or sludge discards into pits, ponds or lagoons, etc.)
- D5 Specially engineered landfill (e.g. placement into lined discrete cells which are capped and isolated from one another and the environment, etc.)
- D6 Release into a water body except seas/oceans
- D7 Release into seas/oceans including sea-bed insertion
- D8 Biological treatment not specified elsewhere in this list which results in final compounds or mixtures which are discarded by means of any of the operations in this list
- D9 Physico-chemical treatment not specified elsewhere in this list which results in final compounds or mixtures which are discarded by means of any of the operations in this list (e.g. evaporation, drying, calcination, etc.)
- D10 Incineration on land
- D11 Incineration at sea
- D12 Permanent storage (e.g. emplacement of containers in a mine, etc.)
- D13 Blending or mixing prior to submission to any of the operations in this list
- D14 Repackaging prior to submission to any of the operations in this list
- D15 Storage pending any of the operations in this list

RECOVERY OPERATIONS (block 11)

- R1 Use as a fuel (other than in direct incineration) or other means to generate energy (Basel/OECD) Use principally as a fuel or other means to generate energy (EU)
- R2 Solvent reclamation/regeneration
- R3 Recycling/reclamation of organic substances which are not used as solvents
- R4 Recycling/reclamation of metals and metal compounds
- R5 Recycling/reclamation of other inorganic materials
- R6 Regeneration of acids or bases
- R7 Recovery of components used for pollution abatement
- R8 Recovery of components from catalysts
- R9 Used oil re-refining or other reuses of previously used oil
- R10 Land treatment resulting in benefit to agriculture or ecological improvement
- R11 Uses of residual materials obtained from any of the operations numbered R1-R10
- R12 Exchange of wastes for submission to any of the operations numbered R1-R11
- R13 Accumulation of material intended for any operation in this list.

| PACKAGING TYPES (block 7) | (block 7) H-CODE AND UN CLASS (block 14) | | |
|--|--|--------|---|
| 1. Drum | UN Class | H-code | Characteristics |
| 2. Wooden barrel | 1 | H1 | Explosive |
| 3. Jerrican | 3 | H3 | Flammable liquids |
| 4. Box | 4.1 | H4.1 | Flammable solids |
| 4. Box 5. Bag | 4.2 | H4.2 | Substances or wastes liable to spontaneous combustion |
| Composite packaging Pressure receptacle | 4.3 | H4.3 | Substances or wastes which, in contact with water, emit flammable gases |
| 8. Bulk | 5.1 | H5.1 | Oxidising |
| 9. Other (specify) | 5.2 | H5.2 | Organic peroxides |
| | 6.1 | H6.1 | Poisonous (acute) |
| MEANS OF TRANSPORT (block 8) | 6.2 | H6.2 | Infectious substances |
| R = Road | 8 | H8 | Corrosives |
| T = Train/rail S = Sea | 9 | H10 | Liberation of toxic gases in contact with air or water |
| A = Air | 9 | H11 | Toxic (delayed or chronic) |
| W = Inland waterways | 9 | H12 | Ecotoxic |
| PHYSICAL CHARACTERISTICS (block 13) 1. Powdery/powder 2. Solid 3. Viscous/paste 4. Sludgy 5. Liquid 6. Gaseous 7. Other (specify) | 9 | H13 | Capable, by any means, after disposal of yielding another material, e.g., leachate, which possesses any of the characteristics listed above |

Further information, in particular related to waste identification (block 14), i.e. on Basel Annexes VIII and IX codes, OECD codes and Y-codes, can be found in a Guidance/Instruction Manual available from the OECD and the Secretariat of the Basel Convention.'

'Movement document for transboundary movements/shipments of waste

| 1. Corresponding to notification No: | | 2. Serial/total number of shipments / | | | |
|---|---|--|--|--|--|
| Exporter — notifier Registration No: | | 4. Importer — consignee Registration No: | | | |
| Name: | • | | Name: | | |
| Address: | | Address: | | | |
| Contact person: | | Contact person: | | | |
| Tel.: F | ax: | Tel.: E-mail: | Fax: | | |
| 5. Actual quantity: Tonnes (Mg): | m³: | 6. Actual date of shipmer | nt· | | |
| 7. Packaging Type(s) (¹): | Number of packages | · · | | | |
| Special handling requirements: (2) | Yes: □ | No: □ | | | |
| 8.(a) 1 st carrier (³): | 8.(b) 2 nd carrier (³): | | 8.(c) Last carrier (³): | | |
| Registration No: | Registration No: | | Registration No: | | |
| Name: | Name: | | Name: | | |
| Address: | Address: | | Address: | | |
| Tel.: | Tel.: Fax: | | Tel.: Fax: | | |
| Fax: E-mail: | E-mail: | | E-mail: | | |
| To be completed by ca | | | | | |
| ii | | | | | |
| Means of transport (1): Date of transfer: | Means of transport (1): Date of transfer: | | Means of transport (1): Date of transfer: | | |
| Signature: | Signature: | | Signature: | | |
| | | T | | | |
| 9. Waste generator(s) — producer(s) (4) (5) (6): | | 12. Designation and com | position of the waste (2): | | |
| Registration No: Name: | | | | | |
| Address: | | | | | |
| Contact person: | | 13. Physical characteristi | os (1): | | |
| | ax: | | | | |
| E-mail: | | 14. Waste identification (| , | | |
| Site of generation (2): | | (i) Basel Annex VIII (or IX (ii) OECD code (if differer | | | |
| 10. Disposal facility □ or Registration No: | recovery facility | (iii) EC list of wastes: | it from (i)). | | |
| Name: | | (iv) National code in count | try of export | | |
| Address: | | (v) National code in coun | | | |
| Contact person: | | (vi) Other (specify): | | | |
| Tel.: | ax: | (vii) Y-code: | | | |
| E-mail: Actual site of disposal/recovery (2) | | (viii) H-code (1): | | | |
| 1 | | (ix) UN class (1): (x) UN number: | | | |
| 11. Disposal/recovery operation(s) | | (xi) UN shipping name: | | | |
| D-code/R-code (1): | | (xii) Customs code(s) (HS) | : | | |
| 15. Exporter's — notifier's/generator's — producer's | (4) declaration: | | | | |
| | ** | certify that legally enforceable | e written contractual obligations have been entered into, that | | |
| | | | ecessary consents have been received from the competent | | |
| Name: Date: | , | Signature: | | | |
| 16. For use by any person involved in the transbour | | | ired | | |
| | | · | | | |
| 17. Shipment received by importer — consignee (if Name: | | Signature: | | | |
| | | | rv | | |
| TO BE COMPLETED BY DISPOSAL/RECOVERY FACILITY 18. Shipment received at disposal facility | | | | | |
| Date of reception: Accepted: | | | described above has been completed | | |
| Quantity received: Tonnes (Mg): m ³ : | | nediately contact | Name: | | |
| Approximate date of disposal/recovery: | con | npetent authorities | Date: | | |
| Disposal/recovery operation (1): | | | | | |
| Name: Date: | | 8 | Signature and stamp: | | |
| Signature: | | | | | |
| (¹) See list of abbreviations and codes on the next page. | | (4) Required by the Basel Conve | ention. | | |
| (2) Attach details if necessary. | 2 (| (5) Attach list if more than one. | | | |
| (3) If more than three carriers, attach information as required in blocks | s σ (a, D, C). | (6) If required by national legislate | uon. | | |

| FOR USE BY CUSTOMS OFFICES (if required by national legislation) | | | | | |
|--|--|---|--|--|--|
| 20. Country of export — dispatch or customs office of exit | | 21. Country of import — destination or customs office of entry | | | |
| The waste described in this movement document left the | | The waste described in this movement document entered the | | | |
| country on: | | country on: | | | |
| Signature: | | Signature: | | | |
| Stamp: | | Stamp: | | | |
| 22. Stamps of customs offices of transit countries | | | | | |
| Name of country: | | Name of country: | | | |
| Exit: | Entry: | Exit: | | | |
| | | | | | |
| Name of country: | | Name of country: | | | |
| Exit: | Entry: | Exit: | | | |
| | | | | | |
| | istoms office of exit cument left the it countries Exit: | 21. Country of Import — destination or The waste described in this movement doccountry on: Signature: Stamp: It countries Name of country: Entry: Name of country: | | | |

List of abbreviations and codes used in the movement document DISPOSAL OPERATIONS (block 11) RECOVERY OPERATIONS (block 11) Deposit into or onto land (e.g. landfill, etc.) Land treatment (e.g. biodegradation of liquid or sludgy discards in soils, etc.) Deep injection (e.g., injection of pumpable discards into wells, salt domes or Use as a fuel (other than in direct incineration) or other means to generate energy (Basel/OECD) — Use principally as a fuel or other means to generate D2 energy (EU) D3 naturally occurring repositories, etc.) Solvent reclamation/regeneration Recycling/reclamation of organic substances which are not used as solvents Recycling/reclamation of metals and metal compounds Surface impoundment (e.g., placement of liquid or sludge discards into pits, D4 R3 ponds or lagoons, etc.) D5 Specially engineered landfill (e.g. placement into lined discrete cells which are R5 Recycling/reclamation of other inorganic materials capped and isolated from one another and the environment, etc.) R6 Regeneration of acids or bases D6 Release into a water body except seas/oceans Recovery of components used for pollution abatement Release into seas/oceans including sea-bed insertion Biological treatment not specified elsewhere in this list which results in final Recovery of components from catalysts Used oil re-refining or other reuses of previously used oil Land treatment resulting in benefit to agriculture or ecological improvement D8 R9 compounds or mixtures which are discarded by means of any of the operations in this list R11 Uses of residual materials obtained from any of the operations numbered R1 to Physico-chemical treatment not specified elsewhere in this list which results in D9 R10 final compounds or mixtures which are discarded by means of any of the Exchange of wastes for submission to any of the operations numbered R1 to R11 operations in this list (e.g., evaporation, drying, calcination, etc.) R13 Accumulation of material intended for any operation in this list D10 Incineration on land Incineration at sea D12 Permanent storage (e.g. emplacement of containers in a mine, etc.) Blending or mixing prior to submission to any of the operations in this list D13 Repackaging prior to submission to any of the operations in this list D15 Storage pending any of the operations in this list PACKAGING TYPES (block 7) H-CODE AND UN CLASS (block 14) 1. Drum **UN Class** H-code Characteristics 2. Wooden barrel Н1 Explosive 3. Jerrican 4. Box 3 НЗ Flammable liquids 5. Bag 4.1 H4.1 Flammable solids 6. Composite packaging 7. Pressure receptacle 4.2 H4.2 Substances or wastes liable to spontaneous 8. Bulk combustion 9. Other (specify) 4.3 H4.3 Substances or wastes which, in contact with water, emit flammable gases MEANS OF TRANSPORT (block 8) H5.1 Oxidising 5.1 R = Road 5.2 H5.2 Organic peroxides T = Train/rai S = Sea 6.1 H6.1 Poisonous (acute) A = Air6.2 H6.2 Infectious substances W = Inland waterways 8 Н8 Corrosives PHYSICAL CHARACTERISTICS (block 13) 9 H₁₀ Liberation of toxic gases in contact with air or water 1. Powdery/powder 2. Solid 9 H11 Toxic (delayed or chronic) 3. Viscous/paste 9 H12 Ecotoxic 4. Sludgy 9 H13 Capable, by any means, after disposal of yielding another material, e.g., leachate, which possesses 5. Liquid 6. Gaseous any of the characteristics listed above 7. Other (specify)

Further information, in particular related to waste identification (block 14), i.e. on Basel Annexes VIII and IX codes, OECD codes and Y-codes, can be found in a Guidance/Instruction Manual available from the OECD and the Secretariat of the Basel Convention.'

NOTE TO THE READER

The institutions have decided no longer to quote in their texts the last amendment to cited acts

Unless otherwise indicated, references to acts in the texts published here are to the version of those acts currently in force.