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II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 14 November 2011

on the signing, on behalf of the European Union, and the provisional application of the Protocol agreed between the European Union and the Republic of Guinea-Bissau setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force

(2011/885/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43 in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(5) To ensure EU vessels can continue their fishing activities, Article 14 of the Protocol provides for it to apply on a provisional basis as from 16 June 2011.

(6) The Protocol should be signed and applied on a provisional basis, pending the completion of the procedures for its conclusion,

HAS ADOPTED THIS DECISION:

Article 1

(1) On 17 March 2008 the Council adopted Regulation (EC) No 241/2008 on the conclusion of the Fisheries Partnership Agreement between the European Community and the Republic of Guinea-Bissau ⁽¹⁾ (hereinafter 'the Partnership Agreement').

The signing of the Protocol agreed between the European Union and the Republic of Guinea-Bissau setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement in force between the two parties (hereinafter 'the Protocol') is hereby authorised on behalf of the Union, subject to its conclusion.

(2) The Protocol determining the fishing opportunities and the financial contribution provided by that Partnership Agreement expired on 15 June 2011.

The text of the Protocol is attached to this Decision.

(3) The Union has negotiated with the Republic of Guinea-Bissau (hereinafter 'Guinea-Bissau') a new Protocol granting EU vessels fishing opportunities in the waters over which Guinea-Bissau exercises sovereignty or jurisdiction in fishing matters (hereinafter 'the Protocol').

Article 2

The President of the Council is hereby authorised to designate the person or persons empowered to sign the Protocol on behalf of the Union.

(4) At the end of those negotiations, the Protocol was initialled on 15 June 2011.

Article 3

The Protocol shall apply on a provisional basis from 16 June 2011, pending the completion of the procedures for its conclusion

⁽¹⁾ OJ L 75, 18.3.2008, p. 49.

Article 4

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

Done at Brussels, 14 November 2011.

For the Council
The President
M. SAWICKI

PROTOCOL

agreed between the European Union and the Republic of Guinea-Bissau setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force

Article 1

Period of application and fishing opportunities

1. For a period of 1 year from 16 June 2011, the fishing opportunities granted pursuant to Articles 5 and 6 of the Agreement shall be as follows:

— crustaceans and demersal species:

a) freezer shrimp trawlers: 4 400 GRT per year;

b) freezer, fin-fish and cephalopod trawlers: 4 400 GRT per year;

— highly migratory species (species listed in Annex 1 to the 1982 United Nations Convention):

c) freezer tuna seiners and longliners: 23 vessels;

d) pole-and-line tuna vessels: 14 vessels;

2. Paragraph 1 shall apply subject to Articles 5 and 6 of this Protocol.

3. Under Article 6 of the Agreement, vessels flying the flag of a Member State of the European Union may fish in Guinea-Bissau fishing zones only if they are in possession of a fishing licence issued under this Protocol in accordance with the Annexes hereto.

Article 2

Financial contribution and specific contribution – Methods of payment

1. The financial contribution referred to in Article 7 of the Agreement shall be fixed, for the period referred to in Article 1 of this Protocol, at EUR 7 million.

2. However, if the use of the fishing opportunities provided for in points (a) and (b) of Article 1(1) of this Protocol by EU vessels improves, the Union will grant an additional amount to Guinea-Bissau proportionate to the increase in the use of the fishing opportunities, within the limits of the fishing opportunities set by this Protocol and up to a maximum of EUR 1

million per year. The two Parties shall agree, within the Joint Committee, and no later than 3 months after the entry into force of this Protocol, to determine the reference period, the base index and the specific payment mechanisms.

3. Paragraph 1 shall apply subject to Articles 5, 6, 7, 8, 9, 11 and 12 of this Protocol.

4. The Union shall pay the financial contribution fixed in paragraph 1 no later than 15 March 2012.

5. Subject to Article 8 of this Protocol, the allocation of this contribution shall be decided within the framework of the Guinea-Bissau Finance Act and the Guinea-Bissau authorities shall have full discretion regarding the use to which it is put.

6. In addition to the amount referred to in paragraph 1, a specific contribution from the Union of EUR 500 000 per year shall be dedicated to the introduction of a health and plant-health system for fishery products. However the two Parties may, where necessary, decide to allocate part of this specific contribution to strengthening monitoring, control and surveillance in Guinea-Bissau fishing zones. This contribution shall be managed in accordance with Article 3 of this Protocol.

7. Without prejudice to Article 3 of this Protocol, the specific contribution referred to in paragraph 6 shall be paid no later than 15 March 2012.

8. The payments provided for in this Article shall be paid into a Public Treasury account opened at Guinea-Bissau's central bank, the references of which shall be notified each year by the Ministry.

Article 3

Specific contribution to help improve the health and plant-health conditions of fishery products and to fisheries monitoring, control and surveillance

1. The specific contribution from the Union mentioned in Article 2(6) of this Protocol shall be put towards, in particular, helping the fisheries sector achieve compliance with health standards and, where necessary, towards Guinea-Bissau's monitoring, control and surveillance policy.

2. Guinea-Bissau shall be responsible for the management of the corresponding amount, based on the identification by the two Parties, by mutual agreement, of the measures to be carried out and the annual programming to attain them.

3. Without prejudice to the objectives identified by the two Parties and in accordance with Articles 8 and 9 of this Protocol, the Parties agree to focus on:

- a) all of the measures which aim to improve the health and plant-health conditions of fishery products, including building up the competent authority, bringing the Centro de Investigação Pesqueira Aplicada (CIPA) up to standards (ISO 9000), training staff and achieving compliance in the necessary legal framework; and, where necessary,
- b) all of the support measures for fisheries monitoring, control and surveillance, including surveillance of Guinea-Bissau waters by sea and by air, setting up a satellite vessel monitoring system (VMS) and improving the legal framework and its application in the event of infringements.

4. A detailed annual report shall be submitted for approval to the Joint Committee provided for in Article 10 of the Agreement.

5. However, the EU reserves the right to suspend payment of the specific contribution provided for in Article 2(6) of this Protocol, from the first year of application of the Protocol, in the event of disputes concerning the programming of measures or where the results obtained, except in exceptional circumstances, do not comply with the programming.

Article 4

Scientific cooperation

1. The two Parties undertake to promote responsible fishing in the Guinea-Bissau fishing zone on the basis of the principles of sustainable management, in particular by promoting cooperation at subregional level on responsible fishing, particularly within the Subregional Fisheries Commission (CSRP).

2. During the period covered by this Protocol, the two Parties shall cooperate to develop certain issues relating to the state of resources in Guinea-Bissau fishing zones; to this end a Joint Scientific Committee shall meet at least once a year, in accordance with Article 4(1) of this Protocol. At the request of one of the Parties and where needed within the framework of this Agreement, other meetings of this Scientific Committee may also be convened.

3. The two Parties, on the basis of the conclusions of the annual joint scientific meeting and of the recommendations and resolutions adopted within the International Commission for the Conservation of Atlantic Tunas (ICCAT), the Fishery Committee for the Eastern Central Atlantic (CECAF) or any other regional or international organisation in this area of which the two Parties are members or in which they are represented, shall consult each other within the Joint Committee

provided for in Article 10 of the Agreement and adopt, where appropriate and by mutual agreement, measures to ensure the sustainable management of fisheries resources.

Article 5

Review of fishing opportunities

1. The fishing opportunities referred to in Article 1 may be increased by mutual agreement provided that the conclusions of the annual joint scientific meeting referred to in Article 4(2) of the Agreement confirm that such an increase will not endanger the sustainable management of Guinea-Bissau resources. In this case the financial contribution referred to in Article 2(1) shall be increased proportionately and pro rata temporis. However, the total amount of the financial contribution paid by the European Union shall not be more than twice the amount indicated in Article 2(1).

2. Conversely, if the Parties agree to adopt measures as referred to in Article 4(2) of the Agreement resulting in a reduction in the fishing opportunities provided for in Article 1, the financial contribution shall be reduced proportionally and pro rata temporis. Without prejudice to Article 8 of this Protocol, this financial contribution could be suspended by the European Union if it is not possible to use any of the fishing opportunities provided for in this Protocol.

3. The allocation of the fishing opportunities among different categories of vessels may also be reviewed by mutual agreement between the Parties, provided that any changes comply with any recommendations made by the annual joint scientific meeting regarding the management of stocks liable to be affected by such redistribution. The Parties shall agree on the corresponding adjustment of the financial contribution where the redistribution of fishing opportunities so warrants.

4. The adjustments of fishing opportunities provided for in paragraphs 1, 2 and 3 shall be decided by mutual agreement between the two Parties in the Joint Committee provided for in Article 10 of the Agreement.

Article 6

New and exploratory fishing opportunities

1. Should EU vessels be interested in fishing activities which are not indicated in Article 1 of this Protocol, the EU shall consult Guinea-Bissau in order to seek authorisation for these new activities. Where appropriate, the Parties shall agree on the conditions applicable to these new fishing opportunities and, if necessary, make amendments to this Protocol and to the Annex hereto.

2. The Parties may carry out exploratory fishing trips in Guinea-Bissau fishing zones, subject to an opinion by the joint scientific committee provided for in Article 4 of the Agreement. To this end, they shall hold consultations whenever one of the Parties so requests and determine, on a case-by-case basis, relevant new resources, conditions and other parameters.

3. Exploratory fishing authorisations shall be granted for testing purposes for a period of no more than 6 months.

4. Where the Parties conclude that the exploratory fishing trips have produced positive results, while preserving ecosystems and conserving living marine resources, new fishing opportunities may be awarded to EU vessels following the consultation procedure provided for in Article 5 of this Protocol and until the expiry of the Protocol and in accordance with the allowable effort. The financial contribution shall be increased in accordance with Article 5 of this Protocol.

5. Catches made during exploratory fishing shall be the property of the vessel owner. Catches of species of a non-regulatory size and species which may not be fished, kept on-board or sold under Guinea-Bissau law shall be prohibited.

Article 7

Suspension and review of the payment of the financial contribution in the event of unusual circumstances

1. The European Union may suspend the payment of the financial contribution and the specific contribution provided for in Article 2 of this Protocol, if:

- (a) unusual circumstances, other than natural phenomena, occur which prevent fishing activities in the exclusive economic zone (EEZ) of Guinea-Bissau; or
- (b) the European Union notes that there has been a violation in Guinea-Bissau of the essential and fundamental elements of human rights and democratic principles as provided for in Article 9 of the Cotonou Agreement.

The suspension decision shall be taken following consultations between the two Parties within a period of 2 months following the request of one of the Parties, and provided that the European Union has paid in full any amounts due at the time of suspension.

2. Payment of the financial contribution and of the specific contribution referred to in Article 2 of this Protocol shall resume as soon as the Parties find, by mutual agreement following consultations, that the circumstances preventing fishing activities are no longer present and/or that the situation allows a resumption of fishing activities.

3. The fishing authorisations granted to EU vessels may be suspended at the same time as the suspension of the payment of the financial contribution under Article 2. If resumed, the validity of these fishing authorisations shall be extended for a period equal to the period of suspension of fishing activities.

Article 8

Contribution of the Partnership Agreement to the implementation of Guinea-Bissau's sectoral fisheries policy

1. A share of 35 % of the financial contribution referred to in Article 2(1), that is, EUR 2 450 000, shall be put towards defining and implementing a sectoral fisheries policy in Guinea-Bissau with a view to introducing sustainable and responsible fishing in its waters.

2. Guinea-Bissau shall be responsible for the management of the corresponding amount, based on the identification by the two Parties, by mutual agreement, of the objectives to be achieved and the annual and multiannual programming to attain them, in particular as regards the sound management of fisheries resources, strengthening scientific research and the monitoring capacity of the competent Guinea-Bissau authorities, and improving production conditions for fishery products.

3. Without prejudice to the objectives identified by the two Parties and in accordance with the priorities of the Strategy of sustainable development of Guinea-Bissau's fisheries sector and with a view to ensuring sustainable and responsible management of the sector, the two Parties agree to focus on the following areas of assistance: monitoring, control and surveillance of fishing activities, scientific research and management and development of fisheries.

Article 9

Methods of implementing the support for Guinea-Bissau's sectoral fisheries policy

1. Without prejudice to Article 8(3) of this Protocol, the European Union and the Ministry shall agree, within the Joint Committee provided for in Article 10 of the Agreement, and from the entry into force of the Protocol, on:

- (a) the annual guidelines steering the implementation of the priorities of Guinea-Bissau fisheries policy aiming to introduce sustainable and responsible fishing, and in particular those referred to in Article 8(2);
- (b) the annual objectives to be achieved and the criteria and indicators to be used to permit an evaluation of the results achieved, on an annual basis. Annex III hereto provides a basic outline of the objectives and performance indicators to be taken into account within the framework of the Protocol.

2. Any amendment of these guidelines, objectives, criteria and evaluation indicators shall be approved by the two Parties within the Joint Committee.

3. The allocation by Guinea-Bissau of the financial support referred to in Article 8(1) of this Protocol shall be communicated to the European Union when the guidelines, objectives, criteria and evaluation indicators are approved within the Joint Committee.

4. The Ministry shall communicate this allocation to the European Union no later than 4 months after the entry into force of this Protocol.

5. The annual report on the implementation of the measures programmed and financed, the results obtained and any difficulties encountered shall be submitted to the Joint Committee provided for in Article 10 of the Agreement for approval.

6. However, the European Union shall reserve the right to adapt or suspend payment of the amount fixed in Article 8(1) of this Protocol, where the annual evaluation of the actual results achieved in terms of implementing the fisheries policy at that point so warrants, and following consultations within the Joint Committee.

Article 10

Economic integration of EU operators in the Guinea-Bissau fisheries sector

1. The Parties undertake to promote the economic integration of EU operators into the fishing industry in Guinea-Bissau as a whole.

2. The Parties undertake to promote the setting up of temporary joint ventures between EU operators and Guinea-Bissau operators with a view to the joint exploitation of fishery resources in the Guinea-Bissau exclusive economic zone (EEZ).

3. 'Temporary Joint ventures' means any association set up on the basis of a contractual agreement of limited duration between EU vessel owners and physical or legal persons in Guinea-Bissau for the purpose of jointly fishing for and exploiting Guinea-Bissau fishing quotas using one or more vessels flying the flag of a Member State of the European Union and sharing the cost profits or losses of the economic activity jointly undertaken.

4. Guinea-Bissau shall award the authorisation required to allow temporary joint ventures set up for the exploitation of fishery resources to operate in its fishing zones.

5. EU vessels which have decided to set up temporary joint ventures under the Protocol in force for the fishing categories referred to in points (a) and (b) of Article 1(1) of this Protocol will be exempt from the payment of licence fees. Moreover,

from the third year of application of the Protocol, Guinea-Bissau shall make financial support available for setting up such temporary joint ventures. The total amount of such support shall not exceed 20 % of the total amount of fees paid by vessel owners under this Protocol.

6. The Joint Committee shall decide the financial and technical provisions allowing for the implementation of this financial support and the promotion of temporary joint ventures within the framework of this Protocol.

Article 11

Disputes – Suspension of application of the Protocol

1. The application of this Protocol may be suspended at the initiative of one of the two Parties after consultation within the Joint Committee if one of the two Parties violates one of the essential and fundamental elements of human rights and democratic principles as provided for in Article 9 of the Cotonou Agreement.

2. Furthermore, any dispute between the Parties over the interpretation of this Protocol and its Annexes or its application shall be the subject of consultations between the Parties within the Joint Committee, in a special meeting if necessary.

3. Application of the Protocol may be suspended at the initiative of one of the Parties if the dispute between the two Parties is deemed to be serious and if the consultations held within the Joint Committee under paragraph 1 have not resulted in an amicable settlement.

4. Suspension of application of this Protocol shall require the interested Party to notify its intention in writing at least 3 months before the date on which suspension is due to take effect.

5. In the event of suspension, the Parties shall continue to consult with a view to finding an amicable settlement to their dispute. Where such settlement is reached, application of the Protocol shall resume and the amount of the financial contribution shall be reduced proportionately and pro rata temporis to the period during which application of the Protocol was suspended.

Article 12

Suspension of application of the Protocol for failure to implement Guinea-Bissau's undertakings on responsible and sustainable fishing

Subject to Article 4 of this Protocol, if Guinea-Bissau fails to honour its undertaking to work towards responsible and sustainable fishing, in particular by complying with annual fisheries management plans drawn up by the Government of Guinea-Bissau, application of this Protocol may be suspended in accordance with Article 11(3) and (4).

Article 13

Suspension of application of this Protocol on grounds of non-payment

Subject to Article 4, if the European Union fails to make the payments provided for in Article 2, application of this Protocol may be suspended on the following terms:

- (a) the competent Guinea-Bissau authorities shall notify the European Commission of the non-payment. The European Commission shall carry out the necessary checks and, where necessary, transmit the payment within no more than 30 working days of the date of receipt of the notification;
- (b) if no payment is made and non-payment is not adequately justified within the period provided for in point (a), the competent Guinea-Bissau authorities shall be entitled to suspend application of this Protocol. They shall inform the European Commission of such action forthwith.

Application of this Protocol shall resume as soon as the payments concerned have been made.

Article 14

Entry into force

1. This Protocol with its Annexes shall enter into force on the date on which the parties notify each other of the completion of the procedures necessary for that purpose.
2. They shall apply with effect from 16 June 2011.
3. This Protocol and its Annexes shall apply for a period of 1 year from its provisional application onwards. The Parties undertake to begin negotiations to conclude a new Protocol aimed at replacing this Protocol on its expiry as soon as possible. The Parties shall attempt to conclude these negotiations within 9 months at most, that is, no later than 15 March 2012.

Съставено в Брюксел на двадесети декември две хиляди и единадесета година.

Hecho en Bruselas, el veinte de diciembre de dos mil once.

V Bruselu dne dvacátého prosince dva tisíce jedenáct.

Udfærdiget i Bruxelles den tyvende december to tusind og elleve.

Geschehen zu Brüssel am zwanzigsten Dezember zweitausendelf.

Kahe tuhande üheteistkümnenda aasta detsembrikuu kahekümnendal päeval Brüsselis.

Έγινε στις Βρυξέλλες, στις είκοσι Δεκεμβρίου δύο χιλιάδες έντεκα.

Done at Brussels on the twentieth day of December in the year two thousand and eleven.

Fait à Bruxelles, le vingt décembre deux mille onze.

Fatto a Bruxelles, addì venti dicembre duemilaundici.

Briselē, divi tūkstoši vienpadsmitā gada divdesmitajā decembrī.

Priimta du tūkstančiai vienuoliktų metų gruodžio dvidešimtą dieną Briuselyje.

Kelt Brüsszelben, a kétezer-tizenegyedik év december havának huszadik napján.

Magħmul fi Brussell, fl-ghoxrin jum ta' Diċembru tas-sena elfejn u hdx.

Gedaan te Brussel, de twintigste december tweeduizend elf.

Sporządzono w Brukseli dnia dwudziestego grudnia roku dwa tysiące jedenastego.

Feito em Bruxelas, em vinte de Dezembro de dois mil e onze.

Întocmit la Bruxelles la douăzeci decembrie două mii unsprezece.

V Bruseli dňa dvadsiateho decembra dvetisícjedenásť.

V Bruslju, dne dvajsetega decembra leta dva tisoč enajst.

Tehty Brysselissä kahdentenakymmenentenä päivänä joulukuuta vuonna kaksituhattayksitoista.

Som skedde i Bryssel den tjugonde december tjugohundraelva.

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



За Република Гвинея Бисау
Por la República de Guinea-Bissau
Za Republiku Guinea-Bissau
For Republikken Guinea-Bissau
Für die Republik Guinea-Bissau
Guinea-Bissau Vabariigi nimel
Για την Δημοκρατία της Γουινέας-Μπισσάου
For the Republic of Guinea-Bissau
Pour la République de Guinée-Bissau
Per la Repubblica di Guinea-Bissau
Gvinejas-Bisavas Republikas vārdā –
Bisau Gvinējos Respublikos vardu
A Bissau-guineai Köztársaság részéről
Għar-Repubblika tal-Ginea Bissaw
Voor de Republiek Guinee-Bissau
W imieniu Republiki Gwinei Bissau
Pela República da Guiné-Bissau
Pentru Republica Guineea-Bissau
Za Guinejsko-bissauskú republiku
Za Republiko Gvinejo Bissau
Guinea-Bissaun tasavallan puolesta
För Republiken Guinea-Bissau



ANNEX I

CONDITIONS GOVERNING FISHING ACTIVITIES BY EU VESSELS IN THE GUINEA-BISSAU FISHING ZONE

CHAPTER I

APPLICATION FOR AND ISSUE OF LICENCES

SECTION 1

General provisions applicable to all vessels

1. Only eligible vessels may obtain a licence to fish in the Guinea-Bissau fishing zone.
2. For a vessel to be eligible, neither the owner, the master nor the vessel itself must be prohibited from fishing in Guinea-Bissau. They must be in order vis-à-vis the Guinea-Bissau authorities insofar as they must have fulfilled all prior obligations arising from their fishing activities in Guinea-Bissau under fisheries agreements concluded with the EU.
3. Any EU vessel applying for a fishing licence may be represented by an agent resident in Guinea-Bissau. The name and address of that representative shall be stated in the licence application.
4. The relevant EU authorities shall present to the Ministry, via the Delegation of the European Union to Guinea-Bissau, an application for each vessel wishing to fish under the Agreement at least 20 days before the date of commencement of the period of validity requested.
5. Applications shall be made to the Ministry on the forms provided for that purpose by the Government of Guinea-Bissau, a specimen of which is attached (Appendix 1). The Guinea-Bissau authorities shall take all the necessary steps to ensure that the data received as part of the licence application are treated as confidential. Those data shall be used exclusively in the context of the implementation of the Fisheries Agreement.
6. All licence applications shall be accompanied by the following documents:
 - proof of payment of the fee for the period of validity of the licence and of the amount provided for in Chapter VII, point 13;
 - any other documents or certificates required under the specific rules applicable to the type of vessel concerned pursuant to this Protocol.
7. The fee shall be paid into the account specified by the Guinea-Bissau authorities.
8. The fees shall include all national and local charges with the exception of port taxes and service charges.
9. Licences for all vessels shall be issued to vessel owners or their representatives via the Delegation of the European Union to Guinea-Bissau within 20 days of receipt of all the documents referred to in point 6 above by the Ministry.
10. If a licence is signed at a time when the offices of the Delegation of the European Union are closed, it shall be sent direct to the vessel's agent and a copy shall be sent to the Delegation of the European Union.
11. Licences shall be issued for a specific vessel and shall not be transferable.
12. However, at the request of the European Union and where force majeure is proven, a vessel's licence shall be replaced by a new licence for another vessel with similar characteristics to those of the first vessel, with no further fee due. However, if the gross registered tonnage (GRT) of the replacement vessel is above that of the vessel to be replaced, the difference in fee shall be paid *pro rata temporis*.
13. The owner of the first vessel, or his or her representative, shall return the cancelled licence to the Ministry via the Delegation of the European Union.
14. The new licence shall take effect on the day that the vessel's owner returns the cancelled licence to the Ministry. The Delegation of the European Union to Guinea-Bissau shall be informed of the licence transfer.
15. The licence must be kept on board at all times, without prejudice to paragraph 1 of Section 2 of Chapter I.
16. The two Parties shall seek agreement for the purposes of promoting the introduction of a licence system based exclusively on the electronic exchange of all the information and documents described above. The two Parties shall seek agreement for the purposes of promoting the rapid replacement of the paper licence by an electronic equivalent such as the list of vessels authorised to fish in Guinea-Bissau's fishing zone.

17. The Parties, acting in the Joint Committee, undertake to replace all references to GRT in this Protocol with GT and to adapt all the provisions affected thereby accordingly. This replacement shall be preceded by appropriate technical consultations between the Parties.

SECTION 2

Special provisions applicable to tuna vessels and surface longliners

1. The licence must be held on board at all times. The European Union shall keep an up-to-date draft list of the vessels for which a fishing licence has been applied for under this Protocol. This draft shall be notified to the Guinea-Bissau authorities as soon as it is drawn up, and then each time it is updated. On receipt of this draft list and of notification of payment of the advance sent to the Guinea-Bissau authorities by the European Commission, the vessel shall be entered by the competent Guinea-Bissau authority on a list of vessels authorised to fish, which shall be notified to the authorities responsible for fisheries inspection and to the Delegation of the European Union to Guinea-Bissau. A certified copy of this list shall then be sent by the Delegation of the European Union to the vessel owner to be kept on board instead of the fishing licence until the licence has been issued by the competent Guinea-Bissau authority.
2. Licences shall be valid for a period of 1 year.
3. Fees shall be calculated for each vessel on the basis of the annual rates laid down in the Fishing Datasheets included in the Protocol. In the case of three-month and six-month licences, the fees shall be calculated *pro rata temporis*, plus 3 % and 2 % respectively to cover recurrent costs in drawing up the licences.
4. Licences shall be issued once the fixed amounts under the corresponding datasheets have been paid to the competent national authorities.
5. The final statement of the fees due for the current year shall be drawn up by the European Commission by 15 June of the following year at the latest on the basis of the catch declarations made by each vessel owner and confirmed by the scientific institutes responsible for verifying catch data in the Member States, such as the Institut de Recherche pour le Développement (IRD), the Instituto Español de Oceanografía (IEO) and the Instituto Português de Investigaç o Mar tima (IPIMAR) via the Delegation of the European Union.
6. The statement shall be sent simultaneously to the Ministry and to the vessel owners.
7. Any additional payments shall be made by the vessel owners to the competent Guinea-Bissau national authorities by 31 July 2012 at the latest, into the account referred to in point 7 of Section 1.
8. However, if the amount of the final statement is lower than the advance fixed in paragraph 3, the resulting balance shall not be reimbursable to the vessel owner.

SECTION 3

Special provisions for trawlers

1. In addition to the documents referred to in paragraph 6 of Section 1 of this Chapter, all licence applications for vessels covered by this Section must be accompanied by:
 - a certified copy of the document drawn up by the Member State certifying the vessel's tonnage in GRT, and
 - a certificate of conformity issued by the Ministry following the technical inspection of the vessel in accordance with paragraph 3.2 of Chapter VIII.
2. Should a licence application be made in respect of a vessel which has already had a licence under this Protocol and the technical characteristics of which remain unchanged, this application shall be presented to the Ministry via the Delegation of the European Union in Bissau, accompanied only by the proof of payment of the fee for the periods in question and of the amount provided for in paragraph 13 of Chapter VII. The Ministry shall authorise the new licence, entering details of the first licence application submitted under the Protocol in force.
3. The following twelve-month periods shall be used for determining the validity of the licences:
 - first period: from 16 June 2011 to 31 December 2011,
 - second period: from 1 January 2012 to 15 June 2012.
4. Licences may not start to run during one annual period and expire during the next.
5. A quarter shall consist of one of the three-month periods beginning 1 January, 1 April, 1 July or 1 October, except for the first and last period of the Protocol which shall run from 16 June 2011 to 30 September 2011 and from 1 April 2012 to 15 June 2012 respectively.

6. Licences shall be valid for 1 year, 6 months or 3 months. They shall be renewable.
7. Licences must be kept on board at all times.
8. Fees shall be calculated for each vessel on the basis of the annual rates laid down in the Fishing Datasheets included in the Protocol. In the case of three-month and six-month licences, the fees shall be calculated *pro rata temporis*, plus 3 % and 2 % respectively to cover recurrent costs in drawing up the licences.

CHAPTER II

FISHING ZONES

EU vessels as referred to in Article 1 of this Protocol shall be authorised to fish in waters beyond 12 nautical miles from the base lines.

CHAPTER III

CATCH REPORTING ARRANGEMENTS FOR VESSELS AUTHORISED TO FISH IN GUINEA-BISSAU WATERS

1. For the purposes of this Annex, the duration of a trip by an EU vessel shall be defined as follows:
 - the period elapsing between entering and leaving Guinea-Bissau's fishing zone, or
 - the period elapsing between entering the Guinea-Bissau fishing zone and a transshipment, or
 - the period elapsing between entering the Guinea-Bissau fishing zone and a landing in Guinea-Bissau.
2. All vessels authorised to fish in Guinea-Bissau waters under the Agreement shall be obliged to communicate their catches to the Ministry in the following manner:
 - 2.1. Declarations shall include the catches made by the vessel during each trip. They shall be sent to the Ministry by fax, mail or e-mail, with a copy sent to the European Commission, via the Delegation of the European Union to Guinea-Bissau, at the end of each trip, and, in any case, before the vessel leaves Guinea-Bissau waters. If this notification is sent by e-mail, electronic receipts shall be sent at once to the vessel by both addressees, with a copy to each other. In the case of tuna vessels, these declarations shall be sent at the end of each marketing year.
 - 2.2. The original of the declarations sent by fax or by e-mail during an annual period of validity of the licence within the meaning of point 2 of Section 2 of Chapter I in the case of tuna vessels, and paragraph 3 of Section 3 in the case of trawlers shall be sent on a physical medium to the Ministry within 45 days following the end of the last trip made during the period. Hard copies shall be sent to the Delegation of the European Union to Guinea-Bissau.
 - 2.3. Tuna vessels and surface longliners shall declare their catches on the corresponding form in the logbook, in accordance with the specimen in Appendix 2. The words 'Outside the Guinea-Bissau EEZ' shall be entered in the logbook in respect of periods during which the vessel is not in Guinea-Bissau waters.
 - 2.4. Trawlers shall declare their catches on a form drawn up in accordance with the specimen in Appendix 3, stating the total catches by species and calendar month or part thereof.
 - 2.5. The forms shall be filled in legibly and signed by the master of the vessel.
3. Where the provisions set out in this Chapter are not complied with, the Government of Guinea-Bissau reserves the right to suspend the licence of the offending vessel until the formalities have been completed and to apply the penalty laid down in current Guinea-Bissau legislation and, in the event of a recurrence, not to renew the licence. The European Commission shall be informed thereof.

The two Parties shall seek agreement for the purposes of establishing a system of electronic exchange of this information.

CHAPTER IV

BY-CATCHES

The level of by-catches for each of the fisheries covered by the Protocol shall be fixed in accordance with Guinea-Bissau legislation and specified in the datasheets for each category.

CHAPTER V

EMBARKING SEAMEN

Vessel owners who have been issued fishing licences under the Agreement shall contribute to the practical vocational training of Guinea-Bissau nationals and to an improvement of the labour market, subject to the conditions and limits set out below:

1. Each trawler owner shall undertake to employ:
 - three seamen-fishermen on vessels of less than 250 GRT;
 - four seamen-fishermen on vessels of 250 to 400 GRT;
 - five seamen-fishermen on vessels of 400 to 650 GRT;
 - six seamen-fishermen on vessels of more than 650 GRT.
2. Vessel owners shall endeavour to take on board additional Guinea-Bissau seamen.
3. Vessel owners shall be free to select through their representatives the seamen they take on board their vessels.
4. The vessel owner or agent shall inform the Ministry of the names of the Guinea-Bissau seamen signed on the vessel concerned, mentioning their position in the crew.
5. The International Labour Organisation (ILO) Declaration on Fundamental Principles and Rights at Work shall apply as of right to seamen signed on by EU vessels. This concerns in particular the freedom of association and the effective recognition of the right to collective bargaining, and the elimination of discrimination in respect of employment and occupation.
6. The employment contracts of Guinea-Bissau seamen, a copy of which shall be given to the signatories, shall be drawn up between the vessel owners' representative(s) and the seamen and/or their trade unions or representatives in consultation with the Ministry. These contracts shall guarantee the seamen the social security cover applicable to them, including life assurance and sickness and accident insurance.
7. The wages of the Guinea-Bissau seamen shall be paid by the vessel owners. They shall be fixed, before licences are issued, by mutual agreement between the vessel owners or their agents and the competent authorities of Guinea-Bissau. However, the wage conditions granted to Guinea-Bissau seamen shall not be lower than those applied to crews from Guinea-Bissau and shall under no circumstances be below ILO standards.
8. All seamen employed aboard EU vessels shall report to the master of the vessel designated on the day before their proposed embarkation date. Where a seaman fails to report at the date and time agreed for embarkation, vessel owners shall be automatically absolved of their obligation to take that seaman on board.
9. Where no Guinea-Bissau seamen are taken on board for reasons other than that referred to in the previous point, EU vessel owners shall be obliged to pay as soon as possible a flat-rate amount for the fishing year equivalent to the wages of the seamen not taken on board.
10. This sum shall be paid into a specific account designated in advance by the competent Guinea-Bissau authorities and shall help fund public vocational training structures in the fisheries sector.

CHAPTER VI

TECHNICAL MEASURES

1. Vessels fishing for highly migratory species shall comply with the measures and recommendations adopted by the ICCAT regarding fishing gear and the technical specifications thereof and all other technical measures applicable to their fishing activities.
2. For trawlers, specific measures are set out in each of the corresponding datasheets.
3. Guinea-Bissau shall apply the closure of fisheries or of a fishery for biological recovery in non-discriminatory fashion to all vessels taking part in those fisheries, whether national, EU or flying the flag of a third country.
4. Based on an impact analysis, if it proves necessary, the two Parties shall agree within the Joint Committee on any corrective measures relating to biological recovery to be applied.

5. In the event that Guinea-Bissau is required to take emergency measures entailing the closure of a fishery outside the period(s) referred to in paragraph 3 above, or to extend the duration of closure beyond the period provided for, the Joint Committee shall be convened to assess the impact of applying such measures to EU vessels.
6. Where application of paragraphs 4 and 5 above entails an increase in the period(s) of closure of fisheries, the two Parties shall hold consultations within the Joint Committee in order to adjust the financial contribution to take account of the reduced fishing opportunities for the EU resulting from such measures.

CHAPTER VII

OBSERVERS ON BOARD TRAWLERS

1. Vessels authorised to fish in Guinea-Bissau waters under the Agreement shall take on board observers appointed by Guinea-Bissau on the terms set out below.
 - 1.1. Each trawler shall take on board an observer appointed by the Ministry responsible for fisheries. In such cases, the port of embarkation shall be determined by common agreement between the Ministry responsible for fisheries and the vessel owners or their representatives.
 - 1.2. The Ministry shall draw up a list of vessels designated to take an observer on board and a list of the appointed observers. These lists shall be kept up to date. They shall be forwarded to the European Commission as soon as they have been drawn up and every 3 months thereafter where they have been updated.
 - 1.3. The Ministry shall inform the vessel owners concerned, or their representatives, of the name of the observer appointed to be taken on board their vessel at the time the licence is issued.
2. The time spent on board by observers shall be fixed by the Ministry, but, as a general rule, it shall not exceed the time required to carry out their duties. The Ministry shall inform the vessel owners or their agents thereof when notifying them of the name of the observer appointed to be taken on board the vessel concerned.
3. The conditions under which observers are taken on board shall be agreed between vessel owners or their representatives and the Guinea-Bissau authorities.
4. Observers shall be taken on board at the beginning of the first trip in the port of Guinea-Bissau and, if the licence is renewed, at a port chosen by the vessel owner.
5. Within 2 weeks and giving 10 days' notice, the vessel owners concerned shall make known at which ports and on what dates they intend to take observers on board.
6. Where observers are taken on board in a foreign country, their travel costs shall be borne by the vessel owner. Should a vessel with a Guinea-Bissau observer on board leave the Guinea-Bissau fishing zone, all measures must be taken to ensure the observer's return as soon as possible at the expense of the vessel owner.
7. If the observer is not present at the time and place agreed or within the 12 hours following the time agreed, vessel owners shall be automatically absolved of their obligation to take the observer on board.
8. Observers shall be treated as officers. Where vessels are operating in Guinea-Bissau waters, they shall carry out the following tasks:
 - 8.1. observe the fishing activities of the vessels;
 - 8.2. verify the position of vessels engaged in fishing operations;
 - 8.3. perform biological sampling in the context of scientific programmes;
 - 8.4. note the fishing gear used;
 - 8.5. verify the catch data for Guinea-Bissau waters recorded in the logbook;
 - 8.6. verify the percentages of by-catches and estimate the discarded catches;
 - 8.7. report fishing data at least once a week by radio, including the quantity of catches and by-catches on board.
9. Masters shall do everything in their power to ensure the physical safety and welfare of observers during the performance of their duties.

10. Observers shall be offered every facility needed to carry out their duties. Masters shall give them access to the means of communication needed for the discharge of their duties, to documents directly concerned with the vessel's fishing activities, including in particular the logbook and the navigation log, and to those parts of the vessel necessary to facilitate the exercise of their tasks.
11. While on board, observers shall:
 - 11.1. take all appropriate steps to ensure that the conditions of their boarding and presence on the vessel neither interrupt nor hamper fishing operations;
 - 11.2. respect the material and equipment on board and the confidentiality of all documents belonging to the vessel.
 - 11.3. draft an activity report to be transmitted to the competent Guinea-Bissau authorities. Those authorities shall send a copy of the report, after processing and within 1 week, to the Delegation of the European Union in Bissau.
12. At the end of the observation period and before leaving the vessel, observers shall draw up an activity report to be transmitted to the competent Guinea-Bissau authorities, with a copy to the European Commission. They shall sign it in the presence of the master, who may add or cause to be added to it in an annex any observations considered relevant, followed by the master's signature. A copy of the report shall be handed to the master when the observers are put ashore.
13. Vessel owners shall bear the cost of accommodating observers in the same conditions as the officers on the vessel, within the confines of the structure of the vessel.

As a contribution to the costs arising from the presence of the observer on board, together with the licence fee the vessel owner shall pay the Guinea-Bissau authorities the sum of EUR 12 per GRT per year *pro rata temporis* for each vessel fishing in Guinea-Bissau waters.
14. The salary and social contributions of the observer shall be borne by the Ministry.

CHAPTER VIII

OBSERVERS ON BOARD TUNA VESSELS

The two Parties shall consult each other, and interested countries, as soon as possible as regards the definition of a system of regional observers and the choice of the competent regional fisheries organisation.

CHAPTER IX

MONITORING

1. In accordance with paragraph 1 of Section 2 of Chapter I, the European Union shall keep an up-to-date list of the vessels to which a fishing licence has been issued under this Protocol. This list shall be notified to the Guinea-Bissau authorities responsible for fisheries inspection as soon as it is drawn up and each time it is updated.
2. Vessels fishing for highly migratory species shall be included on the list referred to in the previous point upon receipt of notification of the advance payment referred to in paragraph 3 of Section 2 of Chapter I of this Annex. A certified copy of the list of tuna vessels shall then be sent to the vessel owner to be kept on board instead of the fishing licence until the licence has been issued by the competent Guinea-Bissau authority.
3. Technical inspection of trawlers
 - 3.1. Once a year and after any alteration in tonnage or changes to the fishing category necessitating the use of a different type of gear, EU trawlers must report to the port of Guinea-Bissau to undergo the inspections required by the legislation in force. Such inspections shall take place within 48 hours of the vessel's arriving in port.
 - 3.2. Once the inspection has been completed satisfactorily, the master of the vessel shall be issued with a certificate having the same period of validity as the licence and which shall be automatically extended in the case of vessels renewing their licence within the year. However, the maximum validity may not exceed 1 year. This certificate must be kept on board at all times.
 - 3.3. The technical inspection shall verify that the vessel's technical characteristics and gear conform to the provisions of the Agreement and that the provisions relating to its crew have been complied with.
 - 3.4. The cost of the inspection shall be borne by the vessel owner at the rates laid down by Guinea-Bissau law. It may not be greater than the amount normally paid by other vessels for the same services.
 - 3.5. Failure by the vessel owner to comply with paragraphs 3.1 and 3.2 above shall result in automatic suspension of the fishing licence until such obligations have been met.

4. Entering and leaving the zone:

All the EU vessels fishing under the Agreement in Guinea-Bissau's fishing zone shall report the date and time and their position to the radio station of the Ministry responsible for fisheries on entering and leaving Guinea-Bissau's fishing zone.

When licences are issued, the Ministry responsible for fisheries shall inform the vessel owners of the call sign, frequency and working hours of the station.

Where they cannot communicate information by radio, vessels may use alternative means, such as telex, telegram or fax (numbers 20.11.57, 20.19.57 and 20.69.50).

4.1. EU vessels shall notify the Ministry at least 24 hours in advance of their intention to enter or leave the Guinea-Bissau fishing zones. For tuna vessels this deadline shall be reduced to 6 hours.

4.2. When notifying leaving, vessels shall also communicate their position and the volume and species in catches on board. This information should preferably be communicated by fax or, for vessels not equipped with a fax, by radio or by e-mail.

4.3. A vessel found to be fishing without having informed the Ministry shall be regarded as a vessel without a licence.

4.4. Vessels shall also be informed of the fax and telephone numbers and e-mail address when the fishing licence is issued.

5. Monitoring procedures

5.1. Masters of EU fishing vessels engaged in fishing activities in Guinea-Bissau waters shall allow and facilitate boarding and the discharge of their duties by any Guinea-Bissau official responsible for the inspection and control of fishing activities.

5.2. These officials shall not remain on board for longer than is necessary for the discharge of their duties.

5.3. Once the inspection and control has been completed, a certificate shall be issued to the master of the vessel.

6. Boarding

6.1. The Ministry shall inform the European Commission via its Delegation to Guinea-Bissau, within no more than 48 hours, of all boardings and penalties imposed on EU vessels in Guinea-Bissau waters.

6.2. The European Commission shall at the same time receive a brief report of the circumstances and reasons leading to the boarding.

7. Statement of boarding

7.1. After the competent Coastal State authority has drawn up a statement, the master of the vessel shall sign it.

7.2. This signature shall not prejudice the rights of the master or any defence which he or she may make with respect to the alleged infringement.

7.3. In accordance with the applicable law, the master may be required to take the vessel to the port indicated by the competent authorities.

8. Information meeting in the event of boarding

8.1. Before any measures regarding the master or the crew of the vessel or any action regarding the cargo and equipment of the vessel are considered, other than those to safeguard evidence relating to the presumed infringement, an information meeting shall be held at the request of the EU, within one working day of the receipt of the above information, between the European Commission and the Ministry, possibly attended by a representative of the Member State concerned.

8.2. At the meeting, the Parties shall exchange any relevant documentation or information helping to clarify the circumstances of the established facts. The vessel owner or his or her representative shall be informed of the outcome of the meeting and of any measures resulting from the boarding.

9. Settlement of boarding

9.1. Before any judicial procedure, an attempt shall be made to resolve the presumed infringement by means of an amicable settlement. This procedure shall end no later than four working days after the boarding.

9.2. In the event of an amicable settlement, the amount of the fine shall be determined in accordance with Guinea-Bissau legislation.

9.3. If the case cannot be settled by amicable settlement and has to be brought before a competent judicial body, a bank security set to take account of the boarding costs and the fines and compensation payable by the Parties responsible for the infringement shall be lodged by the vessel owner with a bank specified by the Ministry.

9.4. The bank security shall be irrevocable until the legal proceedings have been concluded. It shall be released once legal proceedings end without a conviction. Similarly, in the event of a conviction leading to a fine of less than the security lodged, the balance shall be released by the Ministry.

9.5. The vessel shall be released and its crew authorised to leave the port:

- once the obligations arising under the amicable settlement have been fulfilled, or
- when the bank security referred to in paragraph 9.3 above has been lodged and accepted by the Ministry, pending completion of the legal proceedings.

10. Compliance with the rules

All information on infringements committed by EU vessels shall be communicated to the Commission on a regular basis, via the Delegation of the European Union.

11. Transhipment

11.1. All EU vessels wishing to tranship catches in Guinea-Bissau waters shall do so within Guinea-Bissau ports.

11.2. The owners of such vessels must notify the following information to the Ministry at least 24 hours in advance:

- the names of the transshipping fishing vessels,
- the names of the cargo vessels,
- the tonnage by species to be transhipped,
- the day of transhipment.

11.3. Transhipment shall be considered as an exit from the Guinea-Bissau fishing zone. Vessels must therefore submit their catch declarations to the competent authorities and state whether they intend to continue fishing or leave the Guinea-Bissau fishing zone.

11.4. Any transhipment of catches not covered above shall be prohibited in Guinea-Bissau's fishing zone. Any person infringing this provision shall be liable to the penalties provided for by the Guinea-Bissau law in force.

12. Masters of EU vessels engaged in landing or transhipment operations in a Guinea-Bissau port shall allow and facilitate the inspection of such operations by Guinea-Bissau inspectors. Once the inspection has been completed in the port, a certificate shall be issued to the master of the vessel.

CHAPTER X

SATELLITE MONITORING OF FISHING VESSELS

The two Parties shall agree within the Joint Committee on the arrangements for satellite-monitoring of EU fishing vessels fishing under this Agreement where the technical conditions are met.

Appendices

- 1 – Application form for a fishing licence
 - 2 – Statistics on catch and fishing effort
 - 3 – Tuna vessels fishing logbook
-

Appendix 1

Application form for a fishing licence

For official use only	Remarks
Nationality:	
Licence number:	
Date of signing:	
Date of issue:	

APPLICANT

Name of firm:

Trade register No:

First name and surname of applicant:

Date and place of birth:

Occupation:

Address:

.....

Number of employees:

Name and address of agent:

VESSEL

Type of vessel: Registration No:

New name: Former name:

Date and place of construction:

Original nationality:

Length: Width of vessel: Depth:

Gross tonnage: Net tonnage:

Type of building material:

Make of main engine: Type: Engine power:

Propeller: Fixed: ☐ Variable: ☐ Ducted: ☐

Speed:

Call sign: Frequency:

List of sounding, navigation and transmission instruments:

Radar: ☐ Sonar: ☐ Net sounder: ☐VHF: ☐ BLU: ☐ Satellite navigation: ☐ Other

Number of crew:

CONSERVATION

Ice: ☐Ice and refrigeration: ☐Freezing: in brine: ☐dry: ☐in refrigerated sea water: ☐

Total refrigeration power:

Freezing capacity in tonnes/24 hours:

Hold capacity:

TYPE OF FISHING

A. Demersal

Inshore demersal: ☐Deep-sea demersal: ☐

Type of trawl:

cephalopod: ☐shrimp: ☐fin-fish: ☐

Length of trawl: Length of headline:

Mesh size in codend:

Size of mesh in the wings:

Trawling speed:

B. Deep-sea pelagic (tuna)

Pole and line: ☐Number of poles and lines: ☐Seine: ☐

Length of net: Depth of net:

Number of tanks: Capacity (tonnes):

C. Longlines and pots

Surface: ☐Bottom: ☐

Length of line: Number of hooks:

Number of lines:

Number of pots:

SHORE INSTALLATIONS

Address and authorisation No:

.....

Name of firm:

Activities:

Domestic wholesale fish trade: ☐export: ☐

Type and No of wholesale trader's card:

Description of processing and conservation plant:

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

Number of employees:

NB: Indicate affirmative answers by a tick in the appropriate box

Technical remarks

Authorisation of the State ministry

Date	Fishing zone		Number of hauls	Number of hours fishing	Species of fish							Totals							
	Longitude	Latitude																	
16/																			
17/																			
18/																			
19/																			
20/																			
21/																			
22/																			
23/																			
24/																			
25/																			
26/																			
27/																			
28/																			
29/																			
30/																			
TOTAL																			

Appendix 3

TUNA VESSELS FISHING LOGBOOK

[illegible]

ANNEX II

DATASHEET No 1 – FISHING CATEGORY 1:
FREEZER, FIN-FISH AND CEPHALOPOD TRAWLERS

1. Fishing zone

Beyond 12 nautical miles from the base line, including the Guinea-Bissau/Senegal joint management area, extending north to the azimuth 268°.

2. Authorised gear

Standard otter trawls and other selective gear are authorised.

Outriggers are authorised.

In the case of all fishing gear, no methods or devices may be used to seek to obstruct the mesh of the nets or reduce their selective effect. However, in the interests of reducing wear or damage, protective aprons of netting or other material may be attached, but only to the underside of the codend of a bottom trawl. Such aprons must be attached only to the forward and lateral edges of the codend of the trawl. Protective devices may be used for the top of the trawl, but these must consist of a single section of net of the same material as the codend, with the mesh measuring at least 300 millimetres when stretched out.

Doubling of the codend's netting yarn, whether single or multiple, shall be prohibited.

3. Minimum authorised mesh

70 mm

4. Biological recovery

In accordance with Guinea-Bissau law.

In the absence of provisions in Guinea-Bissau law, the two Parties shall agree within the Joint Committee and on the basis of the best available scientific advice approved by the joint scientific meeting, on the most appropriate biological recovery period.

5. By-catches

In accordance with Guinea-Bissau law:

Fin-fish trawlers may not hold on board crustaceans or cephalopods accounting, in each case, for more than 9 % of their total catch in Guinea-Bissau's fishing zone at the end of a trip as defined in Chapter III of the Annex to this Protocol.

Cephalopod trawlers may not hold on board crustaceans accounting for more than 9 % of their total catch in Guinea-Bissau's fishing zone at the end of a trip as defined in Chapter III of the Annex to this Protocol.

Where these percentages exceed the authorised by-catches, penalties shall be imposed in accordance with Guinea-Bissau law.

The two Parties shall consult within the Joint Committee to adjust the authorised rate if necessary.

6. Authorised tonnage/fees

Authorised tonnage (GRT) per year	4 400
Fees in EUR per GRT per year	229 EUR per GRT per year In the case of three-month and six-month licences, the fees shall be calculated <i>pro rata temporis</i> , plus 3 % and 2 % respectively to cover recurrent costs in drawing up the licences.

7. Comments

The conditions governing fishing activity by the vessels shall be as laid down in the Annex to the Protocol.

DATASHEET No 2 – FISHING CATEGORY 2:
SHRIMP TRAWLERS

1. Fishing zone

2. Authorised gear

Standard otter trawls and other selective gear are authorised.

Outriggers are authorised.

In the case of all fishing gear, no methods or devices may be used to seek to obstruct the mesh of the nets or reduce their selective effect. However, in the interests of reducing wear or damage, protective aprons of netting or other material may be attached, but only to the underside of the codend of a bottom trawl. Such aprons must be attached only to the forward and lateral edges of the codend of the trawl. Protective devices may be used for the top of the trawl, but these must consist of a single section of net of the same material as the codend, with the mesh measuring at least 300 millimetres when stretched out.

Doubling of the codend's netting yarn, whether single or multiple, shall be prohibited.

3. Minimum authorised mesh

40 mm

Guinea-Bissau undertakes to amend its legislation within 12 months of the entry into force of this Protocol in order to apply a 50 mm mesh size in accordance with existing law in the subregion, which will apply to all fleets fishing for crustaceans in the Guinea-Bissau fishing zone.

4. Biological recovery

In accordance with Guinea-Bissau law.

In the absence of provisions in Guinea-Bissau law, the two Parties shall agree within the Joint Committee and on the basis of the best available scientific advice approved by the joint scientific meeting, on the most appropriate biological recovery period.

5. By-catches

In accordance with Guinea-Bissau law:

Shrimp trawlers may not hold on board cephalopods or fin-fish accounting, in each case, for more than 50 % of their total catch in Guinea-Bissau's fishing zone at the end of a trip as defined in Chapter III of the Annex to this Protocol.

Where these percentages exceed the authorised by-catches, penalties shall be imposed in accordance with Guinea-Bissau law.

6. Authorised tonnage/fees

Authorised tonnage (GRT) per year	4 400
Fees in EUR per GRT per year	307 EUR per GRT per year In the case of three-month and six-month licences, the fees shall be calculated <i>pro rata temporis</i> , plus 3 % and 2 % respectively to cover recurrent costs in drawing up the licences.

7. Comments

The conditions governing fishing activity by the vessels shall be as laid down in the Annex to the Protocol.

DATASHEET No 3 – FISHING CATEGORY 3:
POLE-AND-LINE TUNA VESSELS

1. Fishing zone:

Beyond 12 nautical miles from the base line, including the Guinea-Bissau/Senegal joint management area, extending north to the azimuth 268°.

Pole-and-line tuna vessels shall be authorised to fish for live bait with a view to carrying out their fishing activities in Guinea-Bissau's fishing zone.

2. Authorised gear and technical measures

Poles and lines.

Purse seines with live bait: 16 mm

Vessels fishing for highly migratory species shall comply with the measures and recommendations adopted by the International Commission for the Conservation of Atlantic Tunas (ICCAT) regarding fishing gear and the technical specifications thereof and all other technical measures applicable to their fishing activities.

3. By-catches:

In accordance with the relevant ICCAT and FAO recommendations, fishing for the basking shark (*Cetorhinus maximus*), white shark (*Carcharodon carcharias*), sand tiger shark (*Carcharias taurus*) and tope shark (*Galeorhinus galeus*) is prohibited.

4. Authorised tonnage/fees

Fee per tonne caught	25 EUR per tonne
Annual flat-rate fee:	500 EUR per 20 tonnes
Number of vessels authorised to fish	14

5. Comments

The conditions governing fishing activity by the vessels shall be as laid down in the Annex to the Protocol.

DATASHEET No 4 – FISHING CATEGORY 4:
FREEZER TUNA SEINERS AND LONGLINERS

1. Fishing zone:

Beyond 12 nautical miles from the base line, including the Guinea-Bissau/Senegal joint management area, extending north to the azimuth 268°.

2. Authorised gear and technical measures

Seine and surface longline.

Vessels fishing for highly migratory species shall comply with the measures and recommendations adopted by the International Commission for the Conservation of Atlantic Tunas (ICCAT) regarding fishing gear and the technical specifications thereof and all other technical measures applicable to their fishing activities.

3. Minimum authorised mesh

Recommended ICCAT standard.

4. By-catches:

In accordance with the relevant ICCAT and FAO recommendations, fishing for the basking shark (*Cetorhinus maximus*), white shark (*Carcharodon carcharias*), sand tiger shark (*Carcharias taurus*) and tope shark (*Galeorhinus galeus*) is prohibited.

5. Authorised tonnage/fees

Fee per tonne caught	35 EUR per tonne
Annual flat-rate fee:	3 150 EUR per 90 tonnes
Number of vessels authorised to fish	23

6. Comments

The conditions governing fishing activity by the vessels shall be as laid down in the Annex to the Protocol.

ANNEX III

Outline of the objectives and performance indicators to be complied with under Articles 3, 8 and 9 of the Protocol

Strategic priorities and objectives	Indicators
1. Improvement of health and hygiene conditions to develop the fisheries sector	
Preparations to obtain export approval	Rules on minimum health and hygiene standards applicable to industrial vessels, canoes and fishing enterprises products drawn up/adopted by Parliament and implemented Competent authority in place Centro de Investigação Pesqueira Aplicada (CIPA) brought up to standards (ISO 9000) Laboratory provided to carry out microbiological and chemical analyses Shrimp monitoring and analysis plan (PNVAR 2008) adopted and incorporated into law Number of health inspectors trained Number of health workers and fisheries ministry staff trained in hygiene standards Approval for export to the European Union obtained
1.1. Modernisation and upgrading health and hygiene of the industrial fleet and the small-scale fleet	Number of industrial vessels brought up to standards Number of wooden canoes replaced with canoes made of more suitable materials (in absolute terms and as a percentage) Number of canoes equipped with iceboxes Increased number of unloading points Small-scale fishing vessels and coastal fishing vessels brought into compliance with health standards (number in absolute terms and as a percentage)
1.2. Developing infrastructure, in particular port infrastructure	Refurbishment of Port of Bissau and extension of fishing port Port fish market for unloading catches from small-scale and industrial fishing developed and restored to standards Port of Bissau brought up to international standards (ratification of OLAS Convention) Wrecks removed from port
1.3. Promoting fisheries products (health and plant-health conditions of the products landed and processed)	Inspection system for fishery products adapted and operational Actors made aware of health and hygiene rules (number of training courses organised and number of people trained) Analytical laboratory operational Number of sites developed for non-industrial landing and processing Promoting technical and commercial partnerships with private operators overseas Eco-labelling system launched for Guinea-Bissau products

Strategic priorities and objectives	Indicators
2. Improving monitoring, control and surveillance of the fishing zone	
Improved legal framework	Agreement adopted between the ministry of fisheries and of defence on surveillance and control National monitoring, control and surveillance plan adopted and implemented
2.1. Strengthening monitoring, control and surveillance	Body of sworn independent inspectors operational (number of people recruited and trained) and corresponding budgetary allocation entered in the finance act Number of days of surveillance at sea: 250 days/year at the end of the period covered by the Protocol Number of inspections in port and at sea Number of aerial inspections Number of statistical bulletins published Radar coverage rate Rate of VMS coverage of the fleet as a whole Training programme adapted to surveillance techniques implemented (number of hours of training, number of technicians trained, etc.)
2.2. Monitoring boarding of vessels	Improving the transparency of the system of boarding, penalties and payments of fines Rules on payment of fines improved and ban introduced on payment of fines other than financial Improvement of system for collection of fines Publication of annual statistics on fines collected Setting up a blacklist of vessels penalised Drawing up of and annual publication of statistics on fines FISCAP annual report published
3. Improving fisheries management	
Managing shrimp and cephalopod fishing effort	Maintaining in 2007 existing agreements with third countries and the European Union. However, if the fishing opportunities granted to third countries remain unused on 1 January 2007, these opportunities shall not be mobilised in 2008 and subsequent years. No fishing opportunities shall be granted to chartering Definitive withdrawal from and formal termination of any agreement with European companies or associations/enterprises within thirty days of the entry into force of this Protocol
3.1. Modernisation and stepping up of fisheries research	Strengthen CIPA research capacities
3.2. Improving information on fishery resources	Annual trawling carried out Number of stocks evaluated Number of research programmes Number of recommendations issued and followed on the state of the main fisheries resources (in particular freezes on fishing and conservation measures for overfished stocks)

Strategic priorities and objectives	Indicators
	Evaluation of annual fishing effort for species which are the subject of a development plan Instrument to manage operational fishing effort (setting up a database, statistical monitoring instruments, networking the services responsible for fleet management, publication of statistical bulletins, etc.)
3.3. Controlled development of fisheries	Adoption of annual management plan for industrial fishing before the start of the year concerned Adoption and implementation of development plan for over-exploited resources Vessel register kept in EEZ, including small-scale fishing Number of development plans drawn up, implemented and evaluated
3.4. Improving the effectiveness of the technical services of the Ministère des Pêches et de l'Economie Maritime (Ministry of Fisheries and the Marine Economy) and the services involved in managing the sector	Administrative capacities strengthened Training and retraining programme drawn up and applied (number of agents trained, number of hours of training, etc.) Mechanisms for coordination, consultation and cooperation with partners strengthened System of data collection and statistical monitoring of fisheries strengthened
3.5. Developing the system for managing licences and monitoring vessels	Number of hours of training for technicians Number of technicians trained Networking of services and statistics

COUNCIL DECISION**of 12 December 2011****on the position to be taken by the European Union in the EEA Joint Committee concerning an amendment to Annex IV (Energy) to the EEA Agreement**

(2011/886/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114(1), 192(1) and 218 (9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area ⁽¹⁾, and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Annex IV to the Agreement on the European Economic Area ⁽²⁾, (hereinafter 'the EEA Agreement') contains specific provisions and arrangements concerning energy.
- (2) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC ⁽³⁾ is to be incorporated into the EEA Agreement.
- (3) Directive 2009/28/EC repeals Directive 2001/77/EC of the European Parliament and of the Council of 27 September 2001 on the promotion of electricity produced from renewable energy sources in the internal electricity market ⁽⁴⁾, which is incorporated into the EEA Agreement and is therefore to be repealed under the EEA Agreement.

- (4) Norway's fulfilment of the target for share of energy from renewable sources in gross final consumption of energy in 2020 must be seen in the context of the initial high share of renewable energy compared to the EU Member States, and the uncertainty associated with supply and demand embedded in the combination of a hydro-based energy production system and a cold climate,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken by the Union in the EEA Joint Committee concerning an amendment to Annex IV (Energy) to the EEA Agreement shall be based on the draft Decision of the EEA Joint Committee attached to this Decision.

Article 2

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

Done at Brussels, 12 December 2011.

For the Council
The President
S. NOWAK

⁽¹⁾ OJ L 305, 30.11.1994, p. 6.

⁽²⁾ OJ L 1, 3.1.1994, p. 3.

⁽³⁾ OJ L 140, 5.6.2009, p. 16.

⁽⁴⁾ OJ L 283, 27.10.2001, p. 33.

DRAFT

DECISION OF THE EEA JOINT COMMITTEE

No ...

of ...

amending Annex IV (Energy) to the EEA Agreement

THE EEA JOINT COMMITTEE,

- (1) the text of point 19 (Directive 2001/77/EC of the European Parliament and of the Council) shall be deleted with effect from 1 January 2012;

Having regard to the Agreement on the European Economic Area, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter 'the Agreement', and in particular Article 98 thereof,

- (2) the following shall be inserted after point 40 (Commission Regulation (EU) No 774/2010):

Whereas:

- (1) Annex IV to the Agreement was last amended by Decision of the EEA Joint Committee No ... of ... ⁽¹⁾.

'41. **32009 L 0028:** Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

- (2) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC ⁽²⁾ is to be incorporated into the Agreement.

The provisions of the Directive shall, for the purposes of this Agreement, be read with the following adaptations:

- (3) Directive 2009/28/EC repeals Directive 2001/77/EC of the European Parliament and of the Council ⁽³⁾, which is incorporated into the Agreement and is therefore to be repealed under the Agreement.

(a) The Directive shall not apply to Liechtenstein.

(b) The second sentence of Article 3(1) shall not apply to the EFTA States.

- (4) Norway's fulfilment of the target for share of energy from renewable sources in gross final consumption of energy in 2020 must be seen in the context of the initial high share of renewable energy compared to the EU Member States, and the uncertainty associated with supply and demand embedded in the combination of a hydro-based energy production system and a cold climate,

(c) The following shall be added in Article 4(2):

"Norway and Iceland shall notify their national renewable energy action plans to the EFTA Surveillance Authority no later than 6 months after the entry into force of Decision of the EEA Joint Committee No ..., incorporating Directive 2009/28/EC."

HAS ADOPTED THIS DECISION:

(d) The following shall be added in Article 22(1):

Article 1

Annex IV to the Agreement shall be amended as follows:

⁽¹⁾ OJ L

⁽²⁾ OJ L 140, 5.6.2009, p. 16.

⁽³⁾ OJ L 283, 27.10.2001, p. 33.

"Norway and Iceland shall submit a report on progress in the promotion and use of energy from renewable sources by 31 December 2013, and every 2 years thereafter. The fifth report, to be submitted by 31 December 2021, shall be the last report required."

- (e) The following shall be added in point A of Annex I:

	Share of energy from renewable sources in gross final consumption of energy, 2005 (S ₂₀₀₅)	Target for share of energy from renewable sources in gross final consumption of energy, 2020 (S ₂₀₂₀)
"Iceland	55,0 %	64 %
Norway	58,2 %	67,5 %" ' "

Article 2

The text of Directive 2009/28/EC in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on ..., provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels,

For the EEA Joint Committee

The President

The Secretaries
to the EEA Joint Committee

(*) [No constitutional requirements indicated.] [Constitutional requirements indicated.]

REGULATIONS

COUNCIL REGULATION (EU) No 1385/2011

of 14 November 2011

on the allocation of the fishing opportunities under the Protocol agreed between the European Union and the Republic of Guinea-Bissau setting out fishing opportunities and the financial contribution provided for in the Fisheries Partnership Agreement between the two parties currently in force

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) On 17 March 2008 the Council adopted Regulation (EC) No 241/2008 on the conclusion of the Fisheries Partnership Agreement between the European Community and the Republic of Guinea-Bissau ⁽¹⁾ (hereinafter 'the Partnership Agreement').

(2) A new Protocol to the Partnership Agreement was initialled on 15 June 2011 (hereinafter 'the new Protocol'). The new Protocol grants EU vessels fishing opportunities in waters in which Guinea-Bissau exercises its sovereignty or jurisdiction as regards fishing.

(3) On 14 November 2011 the Council adopted Decision 2011/885/EU ⁽²⁾ on the signing and provisional application of the new Protocol.

(4) The method for allocating the fishing opportunities among the Member States should be defined for the period when the new Protocol applies.

(5) Article 10(1) of Council Regulation (EC) No 1006/2008 of 29 September 2008 concerning authorisations for fishing activities of Community fishing vessels outside Community waters and the access of third country vessels to Community waters ⁽³⁾ provides that the Commission will inform the Member States concerned if it appears that the fishing opportunities allocated to the Union under the new Protocol are not fully utilised. The absence of a reply within the time limits to be set by

the Council is considered as a confirmation that the vessels of the Member State concerned are not making full use of their fishing opportunities during the period concerned. Those time limits should be set.

(6) Given that the previous Protocol expired on 15 June 2011, this Regulation should enter into force on the date of its publication in the *Official Journal of the European Union* and apply with effect from 16 June 2011,

HAS ADOPTED THIS REGULATION:

Article 1

1. The fishing opportunities fixed under the Protocol attached to Decision 2011/885/EU on the signing and provisional application of that Protocol, shall be allocated between the Member States as follows:

(a) shrimp fishing:

Spain	1 421 GRT
Italy	1 776 GRT
Greece	137 GRT
Portugal	1 066 GRT;

(b) fin-fish/cephalopods:

Spain	3 143 GRT
Italy	786 GRT
Greece	471 GRT;

(c) tuna seiners and surface longliners:

Spain	10 vessels
France	9 vessels
Portugal	4 vessels;

⁽¹⁾ OJ L 75, 18.3.2008, p. 49.

⁽²⁾ See page 1 of this Official Journal.

⁽³⁾ OJ L 286, 29.10.2008, p. 33.

(d) pole-and-line vessels:

Spain 10 vessels

France 4 vessels.

applications for fishing authorisations from any other Member State pursuant to Article 10 of Regulation (EC) No 1006/2008.

The time limit provided by Article 10(1) of that Regulation is set at 10 working days.

2. Regulation (EC) No 1006/2008 shall apply without prejudice to the Fisheries Partnership Agreement between the European Community and the Republic of Guinea-Bissau.

Article 2

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

3. If applications for fishing authorisations from the Member States referred to in paragraph 1 do not cover all fishing opportunities set by the Protocol, the Commission shall consider

It shall apply with effect from 16 June 2011.

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

Done at Brussels, 14 November 2011.

For the Council
The President
M. SAWICKI

DECISIONS

COUNCIL DECISION

of 13 December 2011

on the launch of automated data exchange with regard to DNA data in Lithuania

(2011/887/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime ⁽¹⁾, in particular Article 2(3) and Article 25 thereof,

Having regard to Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA ⁽²⁾, in particular Article 20 and Chapter 4 of the Annex thereto,

Whereas:

- (1) According to the Protocol on Transitional Provisions annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community, the legal effects of the acts of the institutions, bodies, offices and agencies of the Union adopted prior to the entry into force of the Treaty of Lisbon are preserved until those acts are repealed, annulled or amended in implementation of the Treaties.
- (2) Accordingly, Article 25 of Decision 2008/615/JHA is applicable and the Council must unanimously decide whether the Member States have implemented the provisions of Chapter 6 of that Decision.
- (3) Article 20 of Decision 2008/616/JHA provides that decisions referred to in Article 25(2) of Decision 2008/615/JHA are to be taken on the basis of an evaluation report based on a questionnaire. With respect to automated data exchange in accordance with Chapter 2 of Decision 2008/615/JHA, the evaluation report is to be based on an evaluation visit and a pilot run.

- (4) Lithuania has informed the General Secretariat of the Council of the national DNA analysis files to which

Articles 2 to 6 of Decision 2008/615/JHA apply and the conditions for automated searching as referred to in Article 3(1) of that Decision in accordance with Article 36(2) of that Decision.

- (5) According to Chapter 4, point 1.1, of the Annex to Decision 2008/616/JHA, the questionnaire drawn up by the relevant Council Working Group concerns each of the automated data exchanges and has to be answered by a Member State as soon as it believes it fulfils the prerequisites for sharing data in the relevant data category.
- (6) Lithuania has completed the questionnaire on data protection and the questionnaire on DNA data exchange.
- (7) A successful pilot run has been carried out by Lithuania with Austria.
- (8) An evaluation visit has taken place in Lithuania and a report on the evaluation visit has been produced by the Austrian evaluation team and forwarded to the relevant Council Working Group.
- (9) An overall evaluation report, summarising the results of the questionnaire, the evaluation visit and the pilot run concerning DNA data exchange has been presented to the Council,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of automated searching and comparison of DNA data, Lithuania has fully implemented the general provisions on data protection of Chapter 6 of Decision 2008/615/JHA and is entitled to receive and supply personal data pursuant to Articles 3 and 4 of that Decision as from the day of the entry into force of this Decision.

⁽¹⁾ OJ L 210, 6.8.2008, p. 1.

⁽²⁾ OJ L 210, 6.8.2008, p. 12.

Article 2

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

Done at Brussels, 13 December 2011.

For the Council
The President
M. CICHOCKI

COUNCIL DECISION**of 13 December 2011****on the launch of automated data exchange with regard to dactyloscopic data in Lithuania**

(2011/888/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime ⁽¹⁾, in particular Article 25 thereof,

Having regard to Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA ⁽²⁾, in particular Article 20 and Chapter 4 of the Annex thereto,

Whereas:

- (1) According to the Protocol on Transitional Provisions annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community, the legal effects of the acts of the institutions, bodies, offices and agencies of the Union adopted prior to the entry into force of the Treaty of Lisbon are preserved until those acts are repealed, annulled or amended in implementation of the Treaties.
- (2) Accordingly, Article 25 of Decision 2008/615/JHA is applicable and the Council must unanimously decide whether the Member States have implemented the provisions of Chapter 6 of that Decision.
- (3) Article 20 of Decision 2008/616/JHA provides that decisions referred to in Article 25(2) of Decision 2008/615/JHA are to be taken on the basis of an evaluation report based on a questionnaire. With respect to automated data exchange in accordance with Chapter 2 of Decision 2008/615/JHA, the evaluation report is to be based on an evaluation visit and a pilot run.
- (4) According to Chapter 4, point 1.1, of the Annex to Decision 2008/616/JHA, the questionnaire drawn up by the relevant Council Working Group concerns each of the automated data exchanges and has to be answered by

a Member State as soon as it believes it fulfils the prerequisites for sharing data in the relevant data category.

- (5) Lithuania has completed the questionnaire on data protection and the questionnaire on dactyloscopic data exchange.
- (6) A successful pilot run has been carried out by Lithuania with Austria.
- (7) An evaluation visit has taken place in Lithuania and a report on the evaluation visit has been produced by the Austrian evaluation team and forwarded to the relevant Council Working Group.
- (8) An overall evaluation report, summarising the results of the questionnaire, the evaluation visit and the pilot run concerning dactyloscopic data exchange has been presented to the Council,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of automated searching of dactyloscopic data, Lithuania has fully implemented the general provisions on data protection of Chapter 6 of Decision 2008/615/JHA and is entitled to receive and supply personal data pursuant to Article 9 of that Decision as from the day of the entry into force of this Decision.

Article 2

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

Done at Brussels, 13 December 2011.

For the Council
The President
M. CICHOCKI

⁽¹⁾ OJ L 210, 6.8.2008, p. 1.

⁽²⁾ OJ L 210, 6.8.2008, p. 12.

COMMISSION IMPLEMENTING DECISION

of 21 December 2011

as regards a Union financial aid for the year 2012 to European Union reference laboratories

(notified under document C(2011) 9521)

(Only the Danish, Dutch, English, French, German, Italian, Spanish and Swedish texts are authentic)

(2011/889/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field ⁽¹⁾, and in particular Article 31(1) and (2) thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽²⁾, and in particular Article 32(7) thereof,

Whereas:

- (1) European Union reference laboratories may be granted a Union financial aid in accordance with Article 31 of Decision 2009/470/EC.
- (2) Commission Implementing Regulation (EU) No 926/2011 of 12 September 2011 for the purposes of Council Decision 2009/470/EC as regards Union financial aid to the EU reference laboratories for feed and food and the animal health sector ⁽³⁾ provides that the financial aid from the Union is to be granted if the approved work programmes are implemented effectively and that the beneficiaries supply all the necessary information within certain time limits.
- (3) The Commission has assessed the work programmes and corresponding budget estimates submitted by the European Union reference laboratories for the year 2012.
- (4) Accordingly, a Union financial aid should be granted to the European Union reference laboratories designated in order to co-finance their activities to carry out the functions and duties provided for in Article 32 of Regulation (EC) No 882/2004. The Union's financial aid should be at the rate of 100 % of eligible costs as defined in Implementing Regulation (EU) No 926/2011.

(5) For the six European Union reference laboratories designated within the Joint Research Centre, the relationship is laid down in an annual administrative arrangement supported by a work programme and its budget as the Joint Research Centre and the Directorate-General for Health and Consumers are both services of the Commission.

(6) Implementing Regulation (EU) No 926/2011 lays down eligibility rules for the workshops organised by the European Union reference laboratories. It also limits the financial aid to a maximum of 32 participants, 3 invited speakers and 10 representatives of third countries in workshops. Derogations to that limitation should be provided in accordance with Article 15(4) of Implementing Regulation (EU) No 926/2011 to some European Union reference laboratories that need support for attendance by more than 32 participants in order to achieve the best outcome of its workshops. Derogations can be obtained in case a European Union reference laboratory takes the leadership and responsibility when organising a workshop with another European Union reference laboratory.

(7) In accordance with Article 3(2)(a) of Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy ⁽⁴⁾, animal disease eradication and control programmes (veterinary measures) shall be financed from the European Agricultural Guarantee Fund (EAGF). Furthermore, Article 13, second paragraph of that regulation foresees that in duly justified exceptional cases, for measures and programmes covered by Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽⁵⁾, expenditure relating to administrative and personnel costs incurred by Member States and beneficiaries of aid from the EAGF shall be borne by the Fund. For financial control purposes, Articles 9, 36 and 37 of Regulation (EC) No 1290/2005 are to apply.

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

⁽¹⁾ OJ L 155, 18.6.2009, p. 30.

⁽²⁾ OJ L 165, 30.4.2004, p. 1.

⁽³⁾ OJ L 241, 17.9.2011, p. 2.

⁽⁴⁾ OJ L 209, 11.8.2005, p. 1.

⁽⁵⁾ OJ L 224, 18.8.1990, p. 19.

HAS ADOPTED THIS DECISION:

Article 1

1. The European Union grants financial aid to the Laboratoire d'études et de recherches sur la qualité des aliments et sur les procédés agroalimentaires (Lerqap), of the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), Maisons-Alfort, France, for the analysis and testing of milk and milk products.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 328 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 23 000.

Article 2

1. The European Union grants financial aid to the Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Bilthoven, the Netherlands, for the analysis and testing of zoonoses (Salmonella).

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 375 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 35 000.

Article 3

1. The European Union grants financial aid to the Laboratorio de Biotoxinas Marinas, Agencia Española de Seguridad Alimentaria y Nutrición (Ministerio de Sanidad y Política Social), Vigo, Spain, for the monitoring of marine biotoxins.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 283 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 20 000.

Article 4

1. The European Union grants financial aid to the laboratory of the Centre for Environment, Fisheries and Aquaculture Science, Weymouth, United Kingdom, for the monitoring of viral and bacteriological contamination of bivalve molluscs.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 284 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 23 000.

Article 5

1. The European Union grants a financial aid to the Laboratoire d'études et de recherches sur la qualité des aliments et sur les procédés agroalimentaires (Lerqap), of the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), Maisons-Alfort, France, for the analysis and testing of *Listeria monocytogenes*.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 458 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 23 000.

Article 6

1. The European Union grants financial aid to the Laboratoire d'études et de recherches sur la qualité des aliments et sur les procédés agroalimentaires (Lerqap), of the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), 23 avenue du Général-de-Gaulle, Maisons-Alfort Cedex, France, for the analysis and testing of Coagulase positive *Staphylococci*, including *Staphylococcus aureus*.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 356 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 23 000.

Article 7

1. The European Union grants financial aid to the Istituto Superiore di Sanità (ISS), Rome, Italy, for the analysis and testing of *Escherichia coli*, including Verotoxigenic *E. Coli* (VTEC).

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 285 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 22 000.

Article 8

1. The European Union grants financial contribution to the Statens Veterinärmedicinska Anstalt (SVA), Uppsala, Sweden, for the monitoring of *Campylobacter*.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 310 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 40 000.

Article 9

1. The European Union grants financial aid to the Istituto Superiore di Sanità (ISS), Rome, Italy, for the analysis and testing of parasites (in particular *Trichinella*, *Echinococcus* and *Anisakis*).

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 336 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 30 000.

Article 10

1. The European Union grants financial aid to the Fødevarer-institut, Danmarks Tekniske Universitet (DTU), Copenhagen, Denmark, for the monitoring of antimicrobial resistance.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 390 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 36 000.

Article 11

1. The European Union grants financial aid to the Animal Health and Veterinary Laboratories Agency (ex-VLA), Addlestone, United Kingdom, for the monitoring of transmissible spongiform encephalopathies.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 600 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 30 000.

3. By way of derogation from Article 15(4) of Implementing Regulation (EU) No 926/2011, the laboratory referred to in paragraph 1 shall be entitled to claim financial aid for attendance by a maximum of 50 participants at one of its workshops referred to in paragraph 2 of this Article.

Article 12

1. The European Union grants financial aid to the Centre wallon de recherches agronomiques (CRA-W), Gembloux, Belgium, for the analysis and testing of animal proteins in feed-stuffs.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 575 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 30 000.

Article 13

1. The European Union grants financial aid to the Laboratoire d'études et de recherches sur les médicaments vétérinaires et les désinfectants de L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), Fougères, France for residues of certain substances referred to by Annex VII, Section I(12)(b) to Regulation (EC) No 882/2004.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 470 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 25 000.

Article 14

1. The European Union grants financial aid to the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Berlin, Germany, for residues of certain substances referred to by Annex VII, Section I(12)(c) to Regulation (EC) No 882/2004.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 470 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 25 000.

Article 15

1. The European Union grants financial aid to the Istituto Superiore di Sanità, Rome, Italy, for residues of certain substances referred to by Annex VII, Section I(12)(d) to Regulation (EC) No 882/2004.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 285 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 22 000.

Article 16

1. The European Union grants financial aid to the Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg, Germany, for the analysis and testing of residues of pesticides in food of animal origin and commodities with high fat content.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 200 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 22 000.

Article 17

The European Union grants financial aid to the Fødevareinstituttet, Danmarks Tekniske Universitet (DTU), Copenhagen, Denmark, for the analysis and testing of residues of pesticides in cereals and feedingstuffs.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 200 000.

Article 18

The European Union grants financial aid to the Laboratorio Agrario de la Generalitat Valenciana (LAGV)/Grupo de Residuos de Plaguicidas de la Universidad de Almería (PRRG), Spain for the analysis and testing of residues of pesticides in fruits and vegetables, including commodities with high water and high acid content.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 447 000.

Article 19

1. The European Union grants financial aid to the Chemisches und Veterinäruntersuchungsamt (CVUA) Stuttgart, Germany, for the analysis and testing of residues of pesticides by single residue methods.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 370 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 70 000.

3. By way of derogation from Article 15(4) of Implementing Regulation (EU) No 926/2011, the laboratory referred to in paragraph 1 shall be entitled to claim financial aid for attendance by a maximum of 80 participants at one of its workshops referred to in paragraph 2 of this Article.

Article 20

1. The European Union grants financial aid to the Chemisches und Veterinäruntersuchungsamt (CVUA) Freiburg, Germany, for the analysis and testing of dioxins and PCBs in feed and food.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 450 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 60 000.

Article 21

The European Union grants financial aid to the Laboratorio Central de Sanidad Animal de Algete, Algete (Madrid), Spain, for African horse sickness.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 110 000.

Article 22

The European Union grants financial contribution to the Animal Health and Veterinary Laboratories Agency (ex-VLA), New Haw, Weybridge, United Kingdom, for Newcastle disease.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 85 000.

Article 23

The European Union grants financial aid to the AFRC Institute for Animal Health, Pirbright Laboratory, Pirbright, United Kingdom, for swine vesicular disease.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 90 000.

Article 24

The European Union grants financial aid to the Danmarks Tekniske Universitet, Veterinærinstituttet, Afdeling for Fjerkræ, Fisk og Pelsdyr, Århus, Denmark, for fish diseases.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 280 000.

Article 25

The European Union grants financial aid to the Ifremer, La Tremblade, France, for diseases of bivalve molluscs.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 130 000.

Article 26

1. The European Union grants financial aid to the AFRC Institute for Animal Health, Pirbright Laboratory, Pirbright, United Kingdom, for bluetongue.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 259 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 60 000.

Article 27

1. The European Union grants financial aid to the Institut für Virologie der Tierärztlichen Hochschule, Hannover, Germany, for classical swine fever.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 295 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 50 000.

Article 28

1. The European Union grants financial aid to the Centro de Investigación en Sanidad Animal, Valdeolmos, Madrid, Spain, for African swine fever.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 185 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 40 000.

Article 29

1. The European Union grants financial aid to the Institute for Animal Health, Pirbright Laboratory, of the Biotechnology and Biological Sciences Research Council (BBSRC), Pirbright, United Kingdom, for foot-and-mouth disease.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 360 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 40 000.

Article 30

The European Union grants financial aid to the Interbull Centre, Department of Animal Breeding and Genetics, Swedish University of Agricultural Sciences, Uppsala, Sweden, for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 150 000.

Article 31

1. The European Union grants financial aid to the ANSES, Laboratoire d'études et de recherches en pathologie animale et zoonoses, Maisons-Alfort, France, for brucellosis.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 280 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 18 000.

Article 32

The European Union grants financial aid to the Animal Health and Veterinary Laboratories Agency (ex-VLA), New Haw, Weybridge, United Kingdom, for avian influenza.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 380 000.

Article 33

1. The European Union grants financial aid to the Centre for Environment, Fisheries & Aquaculture Science (Cefas), Weymouth Laboratory, United Kingdom, for crustacean diseases.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 105 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 22 000.

Article 34

1. The European Union grants financial aid to the ANSES, Laboratoire d'études et de recherches en pathologie animale et zoonoses/Laboratoire d'études et de recherche en pathologie équine, France, for equine diseases other than African Horse Sickness.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 525 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 30 000.

Article 35

1. The European Union grants financial aid to the ANSES, Laboratoire d'études sur la rage et la pathologie des animaux sauvages, Nancy, France, for rabies.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 250 000.

2. In addition to the maximum amount provided for in paragraph 1, the Union grants financial aid to the laboratory referred to in paragraph 1 for the organisation of workshops. That aid shall not exceed EUR 22 000.

Article 36

The European Union grants financial aid to the Laboratorio de Vigilancia Veterinaria (Visavet) of the Facultad de Veterinaria, Universidad Complutense de Madrid, Madrid, Spain, for tuberculosis.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 285 000.

Article 37

The European Union grants financial aid to the ANSES, Laboratoire de recherches sur la pathologie des abeilles, Sophia-Antipolis, France, for bee health.

For the period from 1 January 2012 to 31 December 2012, that financial aid shall not exceed EUR 300 000.

Article 38

The European Union grants financial aid to the Joint Research Centre of the European Commission, Geel, Belgium, for the following activities regarding the period from 1 January 2012 to 31 December 2012:

- (1) The activities related to heavy metals in feed and food; this aid shall not exceed EUR 237 000.
- (2) The organisation of the workshops by that laboratory, concerning the activities referred to in point 1; this aid shall not exceed EUR 22 000.
- (3) The activities related to Mycotoxins; this aid shall not exceed EUR 238 000.
- (4) The organisation of the workshops by that laboratory, concerning the activities referred to in point 3; this aid shall not exceed EUR 22 000.
- (5) The activities related to Polycyclic Aromatic Hydrocarbons (PAH); this aid shall not exceed EUR 227 000.
- (6) The organisation of the workshops by that laboratory, concerning the activities referred to in point 5; this aid shall not exceed EUR 22 000.

(7) The activities related to additives for use in animal nutrition; this aid shall not exceed EUR 44 000.

(8) The organisation of the workshops by that laboratory, concerning the activities referred to in point 7; this aid shall not exceed EUR 25 000.

Article 39

The European Union grants financial aid to the Joint Research Centre of the European Commission, Ispra, Italy, for the following activities regarding the period from 1 January 2012 to 31 December 2012:

(1) The activities related to material in contact with foodstuffs; this aid shall not exceed EUR 220 000.

(2) The organisation of the workshops by that laboratory, concerning the activities referred to in point 1; this aid shall not exceed EUR 40 000.

(3) The activities related to GMOs; this aid shall not exceed EUR 233 000.

(4) The organisation of the workshops by that laboratory, concerning the activities referred to in point 3; this aid shall not exceed EUR 36 000.

Article 40

The Union's financial aid referred to in Articles 1 to 39 shall be at the rate of 100 % of eligible costs as defined in Implementing Regulation (EU) No 926/2011.

Article 41

This Decision is addressed to the laboratories specified in the Annex.

Done at Brussels, 21 December 2011.

For the Commission

John DALLI

Member of the Commission

ANNEX

- Laboratoire d'études et de recherches sur la qualité des aliments et sur les procédés agroalimentaires (Lerqap), of the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), 23 avenue du Général de Gaulle, 94700 Maisons-Alfort, France,
- Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Anthony van Leeuwenhoeklaan 9, Postbus 1, 3720 BA Bilthoven, The Netherlands,
- Laboratorio de Biotoxinas Marinas, Agencia Española de Seguridad Alimentaria y Nutrición (Ministerio de Sanidad y Política Social), Vigo, Spain, Estacion Maritima, s/n, 36200 Vigo, Spain,
- Laboratory of the Centre for Environment, Fisheries and Aquaculture Science (CEFAS), Weymouth laboratory, Barrack Road, The Nothe, Weymouth, Dorset, DT4 8UB, United Kingdom,
- Istituto Superiore di Sanità (ISS), Viale Regina Elena 299, 00161 Roma, Italy,
- Statens Veterinärmedicinska Anstalt (SVA), Ulls väg 2 B, SE-751 89 Uppsala, Sweden,
- Fødevareinstituttet, Danmarks Tekniske Universitet (DTU), Bülowsvej 27, 1790 Copenhagen V, Denmark,
- Animal Health and Veterinary Laboratories Agency (AHVLA); Weybridge, New Haw, Addelstone Surrey KT15 3NB United Kingdom,
- Centre wallon de recherches agronomiques (CRA-W), chaussée de Namur 24, 5030 Gembloux, Belgium,
- Laboratoire d'études et de recherches sur les médicaments vétérinaires et les désinfectants de L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), Site de Fougères, La Haute Marche, Javéné, BP 90203, 35302 Fougères, France,
- Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Mauerstraße 39-42, 10117 Berlin, Germany,
- Chemisches und Veterinäruntersuchungsamt (CVUA), Postfach 100462, Bissierstraße 5, 79114 Freiburg, Germany,
- Fødevareinstituttet, Danmarks Tekniske Universitet (DTU), Afdeling for Fødevarekemi, Mørkhøj Bygade 19, 2860 Søborg, Denmark,
- Laboratorio Agrario de la Generalitat Valenciana (LAGV)/Grupo de Residuos de Plaguicidas de la Universidad de Almería (PRRG), Ctra. Sacramento s/n, La Canada de San Urbano, 04120 Almería, Spain,
- Chemisches und Veterinäruntersuchungsamt (CVUA), Schaflandstraße 3/2, 70736 Stuttgart, Germany,
- Laboratorio Central de Sanidad Animal, Ministerio de Agricultura, PESCA y Alimentación, Ctra. De Algete km. 8, Valdeolmos, 28110, Algete (Madrid), Spain,
- AFRC Institute for Animal Health, Pirbright Laboratory, Pirbright, Woking, Surrey GU24 0NF, United Kingdom,
- Veterinærinstituttet, Danmarks Tekniske Universitet, Afdelingen for Fjerkræ, Fisk og Pelsdyr, Hangøvej 2, 8200 Århus N, Denmark,
- Ifremer, avenue Mus-de-Loup, Ronce-les-Bains, 17390 La Tremblade, France,
- Institut für Virologie der Tierärztlichen Hochschule, Bischofsholer Damm 15, 30173 Hannover, Germany,
- Centro de Investigación en Sanidad Animal, Ctra. De Algete a El Casar, Valdeolmos 28130, Madrid, Spain,
- Interbull Centre, Department of Animal Breeding and Genetics SLU, Sveriges lantbruksuniversitet, Undervisningsplan E1-27; SE-750 07 Uppsala, Sweden,
- ANSES, Laboratoire d'études et de recherches en pathologie animale et zoonoses, 23 avenue du Général-de-Gaulle, 94 706 Maisons-Alfort Cedex, France,

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- Centre for Environment, Fisheries & Aquaculture Science (Cefas), Weymouth Laboratory, The Nothe, Barrack Road, Weymouth, Dorset DT4 8UB, United Kingdom,
 - ANSES, Laboratoire d'études sur la rage et la pathologie des animaux sauvages, site de Nancy, Domaine de Pixérécourt, 54220 Malzéville, France,
 - Visavet — Laboratorio de vigilancia veterinaria, Facultad de Veterinaria, Universidad Complutense de Madrid, Avda. Puerta de Hierro, s/n. Ciudad Universitaria, 28040 Madrid, Spain,
 - ANSES, Laboratoire de recherches sur la pathologie des abeilles, 105 Route des Chappes, les Templiers, 06902 Sophia Antipolis, France,
 - Joint Research Centre, Retieseweg 111, 2440 Geel (Belgium),
 - Joint Research Centre, Institute for reference materials and measurements, Food safety and quality, Via E. Fermi, 1, 21020 Ispra (Italy),
 - Joint Research Centre, Institute for Health and Consumer Protection, Unit: Physical and chemical exposures, TP 260, Via E. Fermi, 1, 21020 Ispra (Italy),
 - Joint Research Centre, Institute for Health and Consumer Protection, Biotechnology and GMOs Unit, Via E. Fermi, 1, 21020 Ispra (Italy).
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COMMISSION IMPLEMENTING DECISION**of 22 December 2011****providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth**

(2011/890/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare⁽¹⁾, and in particular Article 14(3) thereof,

Whereas:

- (1) Article 14 of the Directive 2011/24/EU assigned the Union to support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States ('the eHealth Network').
- (2) In accordance with Article 14(3) of Directive 2011/24/EU the Commission has an obligation to adopt the necessary rules for the establishment, management and transparent functioning of the eHealth Network.
- (3) Participation in the eHealth Network being voluntary, the Member States should be able to join at any time. For organisational purposes, the Member States wishing to participate should inform the Commission of this intention in advance.
- (4) Personal data of representatives of Member States, experts and observers participating in the Network should be processed in accordance with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁽²⁾ and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)⁽³⁾.

- (5) The 2009 Council conclusions on safe and efficient healthcare through eHealth called for an alignment of eHealth with health strategies and needs at the Union and national levels through the direct involvement of national health authorities. To achieve this, the Council conclusions also called for a high-level mechanism of governance following which a Joint Action⁽⁴⁾ and a Thematic Network were launched in the framework respectively of the Health Programme⁽⁵⁾ and the ICT Policy Support Programme of the Competitiveness and Innovation Programme⁽⁶⁾ (hereafter 'the Joint Action' and 'the Thematic Network'). To ensure coordination, coherence and consistency of the work on eHealth at Union level and to avoid duplication of work, it is appropriate to ensure continuation of the work of the high level mechanism above mentioned within the framework of the eHealth Network, in so far as this work is compatible with the objectives assigned to the Network by Article 14(2) of Directive 2011/24/EU, and to link the Joint Action and the Thematic Network to the eHealth Network.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Committee set up by Article 16 of Directive 2011/24/EU,

HAS ADOPTED THIS DECISION:

*Article 1***Subject matter**

This Decision sets the necessary rules for the establishment, the management and the functioning of the Network of national responsible authorities on eHealth, as provided for by Article 14(1) of Directive 2011/24/EU.

*Article 2***Task**

1. The eHealth Network shall pursue the objectives assigned to it by Article 14(2) of Directive 2011/24/EU.

⁽⁴⁾ Joint Action on eHealth Governance Initiative; Commission Decision C(2010) 7593 of 27 October 2010 on the awarding of grants for proposals for 2010 under the second Health Programme (2008-2013), Contract number 2010/2302.

⁽⁵⁾ Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-2013) (OJ L 301, 20.11.2007, p. 3).

⁽⁶⁾ Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing the Competitiveness and Innovation Framework Programme (2007 to 2013) (OJ L 310, 9.11.2006, p. 15).

⁽¹⁾ OJ L 88, 4.4.2011, p. 45.

⁽²⁾ OJ L 281, 23.11.1995, p. 31.

⁽³⁾ OJ L 201, 31.7.2002, p. 37.

2. In pursuing those objectives the eHealth Network shall work in close cooperation with the Joint Action and the Thematic Network and shall build on the results achieved in the framework of those two activities.

Article 3

Membership — Appointment

1. Members shall be Member States' authorities responsible for eHealth designated by those Member States participating in the eHealth Network.

2. Member States wishing to participate in the eHealth Network shall notify in writing to the Commission this intention as well as the national authority responsible for eHealth they have designated in accordance with Article 14(1) of Directive 2011/24/EU.

3. Each national authority responsible for eHealth shall nominate one representative in the eHealth Network, as well as one alternate, and shall communicate this information to the Commission.

4. The names of Member States' authorities may be published in the Register of Commission expert groups and other similar entities ('the Register').

5. Personal data of representatives of Member States, experts and observers participating in the Network shall be collected, processed and published in accordance with Directives 95/46/EC and 2002/58/EC.

Article 4

Relation between the eHealth Network and the Commission

1. The Commission may consult the eHealth Network on any matter relating to eHealth in the Union, in particular when this is needed in order to provide guidance to the Joint Action and the Thematic Network.

2. Any Member of the eHealth Network may advise the Commission to consult the eHealth Network on a specific question.

Article 5

Rules of procedure

The eHealth Network shall adopt by a simple majority of its Members its own rules of procedure on the proposal by the Commission services, following consultation with the Member States participating in the Network.

Article 6

Operation

1. The eHealth Network may set up sub-groups to examine specific questions on the basis of terms of reference defined by it. Such sub-groups shall be disbanded as soon as their mandate is fulfilled.

2. The eHealth Network shall adopt a multiannual work programme and an evaluation instrument on the implementation of such programme.

3. Members of the eHealth Network and their representatives, as well as invited experts and observers, shall comply with the obligations of professional secrecy laid down by Article 339 of the Treaty and its implementing rules, as well as with the Commission's rules on security regarding the protection of EU classified information, laid down in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom of 29 November 2001 amending its internal Rules of Procedure⁽¹⁾. Should they fail to respect these obligations, the Chair of the eHealth Network may take all appropriate measures.

Article 7

Secretariat of the eHealth Network

1. The Commission shall provide secretarial services for the eHealth Network.

2. Other Commission officials with an interest in the proceedings may attend meetings of the eHealth Network and its sub-groups.

3. The Commission shall publish relevant information on the activities carried out by the eHealth Network either by including it in the Register or via a link from the Register to a dedicated website.

Article 8

Meeting expenses

1. Participants in the activities of the eHealth Network shall not be remunerated by the Commission for their services.

2. Travel and subsistence expenses incurred by participants in the activities of the eHealth Network shall be reimbursed by the Commission in accordance with the provisions in force within the Commission.

Those expenses shall be reimbursed within the limits of the available appropriations allocated under the annual procedure for the allocation of resources.

⁽¹⁾ OJ L 317, 31.12.2001, p. 1.

*Article 9***Entry into force**

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

Done in Brussels, 22 December 2011.

For the Commission

The President

José Manuel BARROSO

COMMISSION DECISION

of 22 December 2011

authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21023-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2011) 9532)***(Only the English text is authentic)****(Text with EEA relevance)**

(2011/891/EU)

THE EUROPEAN COMMISSION,

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

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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 22 June 2005, Dow AgroSciences Europe 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 281-24-236x3006-210-23 cotton ('the application').

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of 281-24-236x3006-210-23 cotton for the same uses as any other cotton with the exception of cultivation. Therefore, in accordance with 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. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) On 15 June 2010, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It considered that cotton 281-24-236x3006-210-23 is as safe as its non-genetically modified counterpart with

respect to potential effects on human and animal health or the environment. Therefore it concluded that it is unlikely that the placing on the market of the products containing, consisting of, or produced from 281-24-236x3006-210-23 cotton 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⁾.

(4) 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.

(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 its 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 and plant establishment are likely to occur.

(6) In order to better describe the monitoring requirements and to comply with the EFSA recommendation, the monitoring plan submitted by the applicant has been modified. Specific measures to limit losses and spillage and to eradicate adventitious cotton populations have been introduced.

(7) Taking into account those considerations, authorisation should be granted for the products.

(8) 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 ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

⁽³⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00863>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

- (9) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from 281-24-236x3006-210-23 cotton. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMO and products other 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.
- (10) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ⁽¹⁾, lays down in Article 4(6) labelling requirements for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (11) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾. The EFSA opinion does not justify the imposition 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 for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (12) 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.
- (13) 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 Article 9(1) and Article 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⁾.

- (14) The applicant has been consulted on the measures provided for in this Decision.
- (15) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chair and the Commission therefore submitted to the Council a proposal relating to these measures.
- (16) Since, at its meeting on 15 December 2011, the Council was unable to reach a decision by qualified majority either for or against the proposal and the Council indicated that its proceedings on this file were concluded, these measures are to be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum*) 281-24-236x3006-210-23, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-24236-5xDAS-21Ø23-5, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 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 DAS-24236-5xDAS-21Ø23-5 cotton;
- (b) feed containing, consisting of, or produced from DAS-24236-5xDAS-21Ø23-5 cotton;
- (c) products other than food and feed containing or consisting of DAS-24236-5xDAS-21Ø23-5 cotton for the same uses as any other cotton with the exception of cultivation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 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 DAS-24236-5xDAS-21Ø23-5 cotton referred to in Article 2(b) and (c).

*Article 4***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in 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 plan in accordance with Decision 2009/770/EC.

*Article 5***Community register**

The information set out 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 Dow AgroSciences Europe, United Kingdom, representing Mycogen Seeds, United States.

*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 Dow AgroSciences Europe, European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 22 December 2011.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) Applicant and Authorisation holder

Name: Dow AgroSciences Europe

Address: European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom

(b) Designation and specification of the products

- (1) Foods and food ingredients containing, consisting of, or produced from DAS-24236-5xDAS-21Ø23-5 cotton.
- (2) Feed containing, consisting of, or produced from DAS-24236-5xDAS-21Ø23-5 cotton.
- (3) Products other than food and feed containing or consisting of DAS-24236-5xDAS-21Ø23-5 cotton for the same uses as any other cotton with the exception of cultivation.

The genetically modified DAS-24236-5xDAS-21Ø23-5 cotton (*Gossypium hirsutum*), as described in the application, expresses the Cry1Ac and Cry1F proteins which confer protection against certain lepidopteran pests and expresses PAT protein, used as a selectable marker, which confers tolerance to the glufosinate-ammonium herbicide.

(c) Labelling

- (1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 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 DAS-24236-5xDAS-21Ø23-5 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 DAS-24236-5xDAS-21Ø23-5 cotton.
- Validated on seeds by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at <https://irmm.jrc.ec.europa.eu/rmcatalogue>
- Reference Material: ERM®-BF422 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <http://gmo-crl.jrc.ec.europa.eu/statusofdosshtm>

(e) Unique identifier

DAS-24236-5xDAS-21Ø23-5

(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 the 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 22 December 2011

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604xGA21 (SYN-IR604-5xMON-00021-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2011) 9533)***(Only the French text is authentic)****(Text with EEA relevance)**

(2011/892/EU)

THE EUROPEAN COMMISSION,

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

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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 31 October 2007, Syngenta Seeds SAS submitted to the competent authority of the United Kingdom 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 MIR604xGA21 maize (the application).

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of MIR604xGA21 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with 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. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) On 18 May 2010, the European Food Safety Authority (EFSA) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It considered that maize MIR604xGA21 is as safe as its

non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore, it concluded that it is unlikely that the placing on the market of the products containing, consisting of, or produced from MIR604xGA21 maize 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⁾.

(4) 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.

(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.

(6) Taking into account those considerations, authorisation should be granted for the products.

(7) 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⁽⁴⁾.

(8) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MIR604xGA21 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMO and products other 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

⁽³⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00832>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

(9) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ⁽¹⁾, lays down in Article 4(6) labelling requirements for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(10) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾. The EFSA opinion does not justify the imposition 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 for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(11) 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.

(12) 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 Article 9(1) and point (c) of Article 15(2) 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⁾.

(13) The applicant has been consulted on the measures provided for in this Decision.

(14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit

laid down by its Chair and the Commission therefore submitted to the Council a proposal relating to these measures.

(15) Since, at its meeting on 15 December 2011, the Council was unable to reach a decision by qualified majority either for or against the proposal and the Council indicated that its proceedings on this file were concluded, these measures are to be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MIR604xGA21, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-IR604-5xMON-00021-9, 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 SYN-IR604-5xMON-00021-9 maize;
- (b) feed containing, consisting of, or produced from SYN-IR604-5xMON-00021-9 maize;
- (c) products other than food and feed containing or consisting of SYN-IR604-5xMON-00021-9 maize for the same uses as any other maize with the exception of cultivation.

Article 3

Labelling

1. 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 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-IR604-5xMON-00021-9 maize referred to in points (b) and (c) of Article 2.

Article 4

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

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 plan in accordance with Decision 2009/770/EC.

Article 5

Community register

The information set out 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 Syngenta Seeds SAS France, representing Syngenta Crop Protection AG, Switzerland.

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 Syngenta Seeds SAS, Chemin de l'Hobit 12, 31790 Saint-Sauveur, France.

Done at Brussels, 22 December 2011.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) Applicant and Authorisation holder

Name: Syngenta Seeds SAS

Address: Chemin de l'Hobit 12, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4058 Basle, Switzerland

(b) Designation and specification of the products

- (1) Foods and food ingredients containing, consisting of, or produced from SYN-IR604-5xMON-00021-9 maize;
- (2) feed containing, consisting of, or produced from SYN-IR604-5xMON-00021-9 maize;
- (3) products other than food and feed containing or consisting of SYN-IR604-5xMON-00021-9 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-IR604-5xMON-00021-9 maize, as described in the application, is produced by crosses between maize containing SYN-IR604-5 and MON-00021-9 events and expresses the Cry3A protein which provides protection against certain coleopteran pests and the mEPSPS protein which confers tolerance to glyphosate herbicide. A *pmi* gene, which allows transformed maize cells to utilise mannose as a sole carbon source, was used as a selectable marker in the genetic modification process for SYN-IR604-5 event.

(c) Labelling

- (1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 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 'maize';
- (2) the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-IR604-5xMON-00021-9 maize referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection

- Event specific real-time quantitative PCR based methods for genetically modified maize SYN-IR604-5 and MON-00021-9 maize validated on SYN-IR604-5xMON-00021-9 maize,
- validated on seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- reference material: ERM®-BF423 (for SYN-IR604-5) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue> and AOCs 0407-A, AOCs 0407-B (for MON-00021-9) accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

(e) Unique identifier

SYN-IR604-5xMON-00021-9.

(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 22 December 2011

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604 (SYN-BTØ11-1xSYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2011) 9535)***(Only the French text is authentic)****(Text with EEA relevance)**

(2011/893/EU)

THE EUROPEAN COMMISSION,

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

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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 31 October 2007, Syngenta Seeds SAS submitted to the competent authority of the United Kingdom an application, in accordance with Article 5 and Article 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 Bt11xMIR604 maize ('the application').

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of Bt11xMIR604 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Article 5(5) and Article 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. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) On 18 May 2010, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No

1829/2003. It considered that maize Bt11xMIR604 is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore it concluded that it is unlikely that the placing on the market of the products containing, consisting of, or produced from Bt11xMIR604 maize 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⁾.

(4) 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 Article 6(4) and Article 18(4) of that Regulation.

(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.

(6) Taking into account those considerations, authorisation should be granted for the products.

(7) 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⁽⁴⁾.

(8) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from Bt11xMIR604 maize. However, in order to ensure the use of the products within the limits of the

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

⁽³⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00833>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMO and products other 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.

- (9) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ⁽¹⁾, lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

- (10) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾. The EFSA opinion does not justify the imposition 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 for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

- (11) 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.

- (12) 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 Article 9(1) and Article 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⁾.

- (13) The applicant has been consulted on the measures provided for in this Decision.

- (14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chair and the Commission therefore submitted to the Council a proposal relating to these measures.

- (15) Since, at its meeting on 15 December 2011, the Council was unable to reach a decision by qualified majority either for or against the proposal and the Council indicated that its proceedings on this file were concluded, these measures are to be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) Bt11xMIR604, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1xSYN-IR6Ø4-5, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 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 SYN-BTØ11-1xSYN-IR6Ø4-5 maize;
- (b) feed containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5 maize;
- (c) products other than food and feed containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5 maize for the same uses as any other maize with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 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 'maize'.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5 maize referred to in Article 2(b) and (c).

Article 4

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in 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 plan in accordance with Decision 2009/770/EC.

Article 5

Community register

The information set out 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 Syngenta Seeds SAS France, representing Syngenta Crop Protection AG, Switzerland.

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 Syngenta Seeds SAS, Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France.

Done at Brussels, 22 December 2011.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) Applicant and Authorisation holder

Name: Syngenta Seeds SAS

Address: Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland

(b) Designation and specification of the products

- (1) Foods and food ingredients containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5 maize;
- (2) feed containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5 maize;
- (3) products other than food and feed containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-BTØ11-1xSYN-IR6Ø4-5 maize, as described in the application, is produced by crosses between maize containing SYN-BTØ11-1 and SYN-IR6Ø4-5 events and expresses the Cry1Ab protein which confers protection against certain lepidopteran pests, the PAT protein which confers tolerance to glufosinate-ammonium herbicides and the Cry3A protein which provides protection against certain coleopteran pests. A *pmi* gene, which allows transformed maize cells to utilize mannose as a sole carbon source, was used as a selectable marker in the genetic modification process for SYN-IR6Ø4-5 event.

(c) Labelling

- (1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 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 'maize';
- (2) the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5 maize referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection

- Event specific real-time quantitative PCR based methods for genetically modified maize SYN-BTØ11-1 and SYN-IR6Ø4-5 maize validated on SYN-BTØ11-1xSYN-IR6Ø4-5 maize.
- Validated on seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofloss.htm>
- Reference Material: ERM®-BF412 (for SYN-BTØ11-1) and ERM®-BF423 (for SYN-IR6Ø4-5) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue>

(e) Unique identifier

SYN-BTØ11-1xSYN-IR6Ø4-5.

(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 the 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 22 December 2011

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2011) 9536)***(Only the French text is authentic)****(Text with EEA relevance)**

(2011/894/EU)

THE EUROPEAN COMMISSION,

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

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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 31 March 2008, Syngenta Seeds SAS submitted to the competent authority of the United Kingdom an application, in accordance with Article 5 and Article 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 Bt11xMIR604xGA21 maize ('the application').

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of Bt11xMIR604xGA21 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Article 5(5) and Article 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. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) On 15 June 2010, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003. It considered that maize Bt11xMIR604xGA21 is as safe as its non-genetically modified counterpart with respect to potential effects

on human and animal health or the environment. Therefore it concluded that it is unlikely that the placing on the market of the products containing, consisting of, or produced from Bt11xMIR604xGA21 maize 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 Article 6(4) and Article 18(4) of that Regulation.

(4) 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.

(5) Taking into account those considerations, authorisation should be granted for the products.

(6) 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⁽⁴⁾.

(7) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from Bt11xMIR604xGA21 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMO and products other 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

⁽³⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00834>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

- (8) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ⁽¹⁾, lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾. The EFSA opinion does not justify the imposition 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 for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (10) 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.
- (11) 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 Article 9(1) and Article 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⁾.
- (12) The applicant has been consulted on the measures provided for in this Decision.
- (13) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chair and the Commission therefore submitted to the Council a proposal relating to these measures.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

- (14) Since, at its meeting on 15 December 2011, the Council was unable to reach a decision by qualified majority either for or against the proposal and the Council indicated that its proceedings on this file were concluded, these measures are to be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) Bt11xMIR604xGA21, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 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 SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;
- (b) feed containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;
- (c) products other than food and feed containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize for the same uses as any other maize with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 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 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize referred to in Article 2(b) and (c).

Article 4

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in 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 plan in accordance with Decision 2009/770/EC.

Article 5

Community register

The information set out 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 Syngenta Seeds SAS France, representing Syngenta Crop Protection AG, Switzerland.

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 Syngenta Seeds SAS, Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France.

Done at Brussels, 22 December 2011.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder**

Name: Syngenta Seeds SAS

Address: Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland

(b) **Designation and specification of the products**

- (1) Foods and food ingredients containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;
- (2) feed containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;
- (3) products other than food and feed containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize, as described in the application, is produced by crosses between maize containing SYN-BTØ11-1, SYN-IR6Ø4-5 and MON-ØØØ21-9 events and expresses the Cry1Ab protein which confers protection against certain lepidopteran pests, a PAT protein which confers tolerance to glufosinate-ammonium herbicides, the Cry3A protein which provides protection against certain coleopteran pests and the mEPSPS protein which confers tolerance to glyphosate herbicide. A *pmi* gene, which allows transformed maize cells to utilize mannose as a sole carbon source, was used as a selectable marker in the genetic modification process for SYN-IR6Ø4-5 event.

(c) **Labelling**

- (1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 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 'maize';
- (2) the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize referred to in Article 2(b) and (c) of this Decision.

(d) **Method for detection**

- Event specific real-time quantitative PCR based methods for genetically modified maize SYN-BTØ11-1, SYN-IR6Ø4-5 and MON-ØØØ21-9 maize validated on SYN-BTØ11-1xSYN-IR6Ø4-5 xMON-ØØØ21-9 maize.
- Validated on seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- Reference Material: ERM®-BF412 (for SYN-BTØ11-1) and ERM®-BF423 (for SYN-IR6Ø4-5) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue> and AOCS 0407-A, AOCS 0407-B (for MON-ØØØ21-9) accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

(e) **Unique identifier**

SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9.

(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 the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

2011/894/EU:

- ★ **Commission Decision of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council** (*notified under document C(2011) 9536*) ⁽¹⁾ 64



⁽¹⁾ Text with EEA relevance

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